

Device-Related Safety Signals and Regulatory Lifecycle of Implanted Deep Brain Stimulation Systems for Movement Disorders: A Multi- Database Analysis of FDA Public Records

Jakub Wiśniewski

Nicolaus Copernicus Hospital

Anna Barbara Marcinkowska

anna.marcinkowska@gumed.edu.pl

Nicolaus Copernicus Hospital

Oskar Liczbik

Nicolaus Copernicus Hospital

Paweł Jan Winklewski

Medical University of Gdańsk

Wojciech Wasilewski

Nicolaus Copernicus Hospital

Research Article

Keywords: deep brain stimulation, implantable neurostimulation devices, device reliability, hardware failure modes, post-market surveillance, regulatory considerations

Posted Date: October 4th, 2026

DOI: <https://doi.org/10.21203/rs.3.rs-11020975/v1>

License:   This work is licensed under a Creative Commons Attribution 4.0 International License. [Read Full License](#)

Additional Declarations: No competing interests reported.

Abstract

Background and Objectives: Deep brain stimulation (DBS) systems are long-dwelling, modular implantable electronic assemblies of intracranial leads, extension cables, connectors, implantable pulse generators (IPGs), chargers, and programming interfaces, with distinct failure and lifecycle behaviour. We characterized device-related safety signals and regulatory lifecycle activity for these systems using public United States Food and Drug Administration (FDA) records.

Methods: We performed a descriptive, multi-database analysis of FDA Product Classification, Manufacturer and User Facility Device Experience (MAUDE)/openFDA Device Event, Device Recall, and Premarket Approval (PMA) records, using DBS product codes MHY, NHL, PJS, and SGS. MAUDE reports (2015–2025) were analyzed, recall records were curated at the event level, and PMA supplement records were classified by lifecycle domain. Narrative categories were validated against a manually adjudicated 400-report reference sample.

Results: The MAUDE layer included 39,867 report-level records (51.4% malfunction, 47.8% injury, 0.8% death-coded), dominated by product code MHY (36,180 reports, 90.8%); no SGS-coded records were retrieved. Validation supported infection/wound/erosion, explant/removal, hemorrhage/stroke-like event, and impedance/circuit problem as the most defensible categories. Event-type composition differed by calendar year ($\chi^2=991.6$, $df = 20$, $p < 0.001$) and product code ($\chi^2=1459.7$, $df = 4$, $p < 0.001$), with small effect sizes (Cramer's $V = 0.11$ – 0.14). The curated recall layer comprised 22 events involving leads, extensions, IPGs, chargers, programmer software, and labeling; the 716-record PMA layer contained a distinct design, component, and material modification domain.

Conclusions: Public FDA

records provide a structured, device-level view of hardware and system-integrity signals across the DBS product lifecycle, but cannot estimate complication incidence, patient-level risk, comparative device safety, or causality.

1. Introduction

Deep brain stimulation (DBS) is an established implantable neuromodulation therapy for selected movement disorders, including Parkinson's disease, essential tremor, and dystonia [1–8]. From a device-engineering perspective, a DBS system is a modular electromechanical assembly rather than a single implant. It comprises intracranial leads carrying metallic stimulating contacts within polymeric insulation, extension cables and connector blocks that cross mobile cervical tissue planes, a hermetically sealed implantable pulse generator (IPG) with a primary-cell or rechargeable power source, transcutaneous chargers, patient and clinician programmers, embedded and application software, and indication- and magnetic resonance imaging (MRI)-specific labeling [9, 10]. These assemblies remain in situ for years to decades under continuous electrical loading, repeated mechanical flexion, and sustained exposure to a saline biological environment, and they may require reprogramming, revision, component replacement, explantation, or management of hardware-related complications [11–16].

The clinical evidence base for DBS is substantial, particularly for Parkinson's disease, essential tremor, and dystonia [2–8, 17]. Nevertheless, randomized trials, prospective cohorts, and institutional case series have inherent limits for post-market device surveillance. They are usually not designed to detect low-frequency hardware failures such as conductor fracture, insulation breach, connector discontinuity, or charging-subsystem faults, nor accessory-specific issues, software or communication anomalies, recall-level regulatory actions, or long-term lifecycle patterns across successive device generations. Reliability assessment and regulatory evaluation of implantable medical electronics therefore depend substantially on post-market data sources that operate at the scale of the installed base [34, 35].

Public FDA records offer a complementary perspective. The United States Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) system contains medical device reports (MDRs) submitted by mandatory and voluntary reporters and is queryable through openFDA [18, 19]. However, MAUDE is a passive surveillance database. FDA explicitly cautions that MDR data cannot be used to establish event rates, evaluate changes in event rates over time, or compare event rates between devices because denominator data, reporting completeness, exposure time, and clinical adjudication are unavailable [20].

Previous MAUDE-based DBS studies have focused on complications in Parkinson's disease, parkinsonian symptoms without tremor, electromagnetic interference, and DBS for refractory obsessive-compulsive disorder [21–24]. They show that MAUDE is useful for signal detection and hypothesis generation, but they also highlight the constraints of drawing conclusions from a single passive-reporting source. The present study extends this work by combining a product-code-defined DBS case definition, MAUDE event reports, manual narrative validation, recall-event curation, and PMA/supplement lifecycle mapping within a single FDA public-record analysis.

An integrated public-record analysis is useful only when each FDA database is read within its own evidentiary limits. MAUDE records describe report-level adverse-event signals; recall records identify regulatory safety actions; PMA records document regulatory lifecycle activity; and Product Classification records anchor the case definition in FDA terminology rather than trade names alone. Figure 1 summarizes the analytical framework.

The objective of this study was to analyze FDA public records for DBS systems used in movement disorders across four linked regulatory data layers. We aimed to: (1) define a regulatory product-code case definition; (2) characterize MAUDE/openFDA Device Event records from 2015 to 2025; (3) validate narrative-derived MAUDE safety-signal categories; (4) identify curated FDA Device Recall events involving DBS systems; and (5) reconstruct the PMA/supplement lifecycle of major DBS system families. The study was descriptive, surveillance-oriented, and regulatory-lifecycle focused, with exploratory tests of reporting-composition heterogeneity. It was not designed to estimate incidence, determine causality, model patient-level risk, or compare manufacturer safety. The intended contribution is methodological and device-oriented. We aimed to show how component-, material-, and software-related failure signals for an implanted neurostimulation system can be extracted from public regulatory records without overstating what passive reporting can support.

2. Materials and Methods

2.1. Study Design

This retrospective, descriptive, report-level analysis used publicly available FDA records for DBS systems used in movement disorders. Four database layers were integrated: FDA Product Classification, MAUDE/openFDA Device Event, FDA/openFDA Device Recall, and FDA/openFDA PMA records. Table 2 summarizes the role and native analytical unit of each layer.

Table 2
Integrated FDA database layers used in the study.

Database layer	Curated entities	Analytical unit	Role	Interpretive limit
FDA Product Classification	4	Product code	Defines the movement-disorder DBS case definition and exclusion boundary.	Classification records define regulatory scope, not clinical outcomes.
MAUDE/openFDA Device Event	39,867	MDR report	Report-level post-market safety-signal characterization.	Cannot estimate incidence, patient-level risk, causal attribution, or manufacturer-comparative safety.
FDA/openFDA Device Recall	22	Recall event grouped by res_event_number	Regulatory safety-action mapping.	Recall events are regulatory actions, not clinical event frequencies.
FDA/openFDA PMA	716	PMA/supplement record	Regulatory lifecycle reconstruction.	PMA supplements are regulatory lifecycle records, not adverse-event reports.

The primary post-market safety window was 1 January 2015 to 31 December 2025. MAUDE records were indexed by FDA date_received. Recall records were indexed by event_date_initiated. PMA records were analyzed across all available openFDA PMA records and then stratified into records before 2015 versus 2015–2025. Public FDA records were queried and verified at data lock on 14 June 2026. The study was not preregistered. Reporting was structured using STROBE/RECORD principles where applicable to routinely collected administrative and registry-type data, with adaptation to the public regulatory-database context [25].

2.2. Regulatory Case Definition

The device scope was defined using FDA Product Classification records [26–29]. The primary movement-disorder DBS product-code set comprised MHY, NHL, PJS, and SGS. Psychiatric DBS indications, including obsessive-compulsive disorder-related product codes, were excluded from the primary analysis. Table 1 provides the case definition.

Table 1
FDA product-code case definition for movement-disorder DBS systems.

Product code	FDA device name	Scope	Primary analysis status	Rationale
MHY	Stimulator, electrical, implanted, for parkinsonian tremor	Parkinsonian tremor / tremor-control DBS	Included	Movement-disorder DBS code used for the primary MAUDE, recall, and PMA scope.
NHL	Stimulator, electrical, implanted, for parkinsonian symptoms	Advanced levodopa-responsive Parkinsonian symptoms; GPi/STN stimulation in the FDA classification definition	Included	Movement-disorder DBS code used for Parkinsonian symptoms and the primary study scope.
PJS	Stimulator, electrical, implanted, for essential tremor	Essential tremor DBS	Included	Movement-disorder DBS code used for essential tremor and the primary study scope.
SGS	Deep brain stimulation for the treatment of dystonia	Dystonia DBS	Included in prespecified case definition; zero MAUDE records retrieved in 2015–2025	Movement-disorder DBS code retained to preserve the dystonia scope, despite zero MAUDE reports in the extracted dataset.
OLM	Deep brain stimulator for obsessive-compulsive disorder	Psychiatric DBS; outside movement-disorder scope	Excluded from primary analysis	Excluded because the primary research question focused on movement disorders.

2.3. Data Sources and Analytical Units

Each FDA data layer was analyzed according to the unit in which it is generated and interpreted. Product Classification records defined the case definition. MAUDE/openFDA Device Event records supported report-level safety-signal characterization. Device Recall records supported regulatory safety-action mapping. PMA records supported regulatory lifecycle reconstruction. Table 2 lists the integrated database layers.

2.4. MAUDE/openFDA Device Event Retrieval and Narrative Handling

MAUDE/openFDA Device Event records were retrieved for FDA date_received from 2015-01-01 to 2025-12-31 using product codes MHY, NHL, PJS, and SGS [18, 19, 26–29]. Retrieval was performed in monthly chunks to avoid endpoint pagination constraints and to preserve a query manifest. Raw JSON files were saved before parsing.

The primary MAUDE unit of analysis was the unique MDR report. Deduplication used mdr_report_key and report_number. In the extracted dataset, this procedure did not reduce the record count, leaving 39,867 report-level MAUDE records. Because MAUDE does not provide reliable patient identifiers, we did not attempt to

consolidate potentially related reports submitted by different reporters or at different times. The dataset is therefore a report-level corpus, not a patient-level cohort.

Primary event-description text was extracted for narrative analysis. Manufacturer narratives were retained for audit but were not used as the primary validation material because their structure and terminology were inconsistent and because they may include post hoc manufacturer assessments or causal framing rather than the original clinical account. Automated dictionary flags were generated for clinically relevant narrative categories, including infection/wound/erosion, explant/removal, replacement/exchange, revision/reoperation, lead or electrode problem, impedance/circuit problem, hemorrhage/stroke-like event, loss of efficacy, and pain/symptom recurrence. These automated categories were treated as candidate report-level signals, not as clinically adjudicated complications.

2.5. Manual Validation

A stratified validation sample of 400 deduplicated MAUDE reports was independently reviewed by two clinical reviewers (J.W. and A.B.M.) against predefined narrative-category definitions. Sampling was designed to include reports across FDA event types and automated narrative-category strata, thereby avoiding a purely prevalence-weighted sample dominated by the largest product-code family. Allowed labels were Yes, No, Unclear, and Not assessable. Disagreements were resolved by consensus adjudication, and the consensus labels were treated as the manual reference standard for evaluating automated dictionary-derived classifications. Across the 400 validated reports, automated category flags and consensus manual reference labels were compared at the level of individual candidate categories (6,400 paired category-level assessments in total), with an overall percent agreement of 87.5%. The reported kappa values in Table 3 quantify agreement between automated dictionary flags and the consensus manual reference labels for each individual category; they should not be interpreted as pre-consensus inter-rater agreement between the two clinical reviewers.

Table 3
Validation-informed MAUDE narrative categories selected for main-text interpretation.

Category	Auto-positive n	% of MAUDE reports	Sens. %	Spec. %	PPV %	F1%	Kappa %	Presentation
Revision/reoperation	7530	18.9	75.3	90.5	64.7	69.6	49.8	Cautious
Explant/removal	10583	26.5	98.8	91.5	76.6	86.3	79.8	Main validated
Replacement/exchange	15096	37.9	87.8	82.8	63.2	73.5	52.2	Cautious
Infection/wound/erosion	5455	13.7	88.9	98.8	92.3	90.6	85.9	Main validated
Impedance/circuit problem	6554	16.4	75.3	95.1	80.3	77.7	71.4	Main validated
Hemorrhage/stroke-like event	1504	3.8	80.0	99.7	94.1	86.5	73.7	Main validated

Validation performance was summarized with sensitivity, specificity, positive predictive value (PPV), negative predictive value, F1 score, percent agreement, and Cohen's kappa when category prevalence allowed stable

estimation. Categories were emphasized in the main text only when validation performance and clinical interpretability supported that use. Lower-performing categories were reported cautiously or limited to supplementary interpretation.

2.6. FDA Device Recall Retrieval and Curation

FDA/openFDA Device Recall records were retrieved for event_date_initiated from 2015-01-01 to 2025-12-31 [30]. Retrieval combined product-code queries with keyword-expanded DBS trade-name queries, since recall records may encode affected products, accessories, and system components differently from MAUDE event records. The raw recall search identified 70 records. After deduplication, 40 candidate product records remained. Manual curation retained records when the recalled product, accessory, labeling, or corrective action was directly related to a DBS system or DBS PMA family. False-positive keyword hits, including non-neuromodulation uses of “DBS” and records unrelated to movement-disorder DBS systems, were excluded. Product codes outside the primary MAUDE case definition, including accessory-related codes such as LGW or MRU, were retained only in the recall layer when the record was clearly linked to a DBS system or PMA family; these codes were not added to the primary MAUDE case definition.

The primary recall unit was the recall event grouped by res_event_number, to avoid overcounting multi-product recalls. Product-level recall records were retained for component-level description. The curation sequence was therefore 70 raw recall records, 40 deduplicated candidate product records, 24 retained product-level records, and 22 unique recall events.

2.7. FDA PMA Retrieval and Lifecycle Curation

FDA/openFDA PMA records were retrieved using product-code and keyword-expanded DBS queries [31]. Retrieval was not restricted to 2015–2025 because the aim was to reconstruct regulatory lifecycle history. Curated movement-disorder DBS PMA families were mapped to the principal manufacturer-associated families represented in FDA records: P960009 (Medtronic-associated DBS systems), P140009 (Abbott/St. Jude-associated DBS systems), and P150031 (Boston Scientific-associated DBS systems). PMA records were analyzed both across all available records and within the 2015–2025 post-market window.

PMA records were assigned to pragmatic lifecycle domains: original approval/base PMA; manufacturing/process/quality system; design/component/material modification; labeling/indications/instructions; postapproval study/condition of approval; administrative/reporting; and other/unclear. This author-derived taxonomy was defined before final tabulation and used only for descriptive regulatory-lifecycle interpretation, not for clinical or causal classification. Inter-rater reliability was not assessed for PMA lifecycle-domain assignment.

2.8. Manufacturer-Associated Group Harmonization

Manufacturer-associated groups were used only for exploratory reporting-composition analyses and for recall/PMA contextualization. Harmonization used FDA manufacturer-name fields where available, product-name and PMA-family context, and manual normalization of common legacy or subsidiary names. St. Jude Medical records were pooled with Abbott/St. Jude-associated records because of acquisition-related continuity of DBS product families. Boston Scientific-associated and Medtronic-associated records were harmonized in the same way. Records that could not be attributed with sufficient confidence were excluded

from manufacturer-associated chi-square testing. These groupings are descriptive and partly brand-informed; they should not be read as manufacturer safety rankings.

2.9. Exploratory Statistical Analysis

The primary analysis was descriptive. Exploratory inferential tests were used to assess whether reporting composition varied across observable strata. These analyses were not intended to estimate complication incidence, patient-level risk, causality, or comparative manufacturer safety.

Pearson chi-square tests of independence assessed event-type composition across calendar years, product codes, and manufacturer-associated groups. Sparse “Other” event-type counts were excluded from chi-square analyses and not merged with other categories. Cramer’s V quantified effect size. Spearman rank correlation assessed monotonic annual report-volume trends. The death-coded report proportion was examined using annual aggregated counts, not patient-level data, in both Spearman correlation and an unadjusted grouped-binomial logistic model with calendar year as a continuous predictor. This model used 11 annual observations, did not adjust for patient-level or device-level covariates, and was interpreted only as exploratory reporting-composition analysis. No denominator, implant volume, exposure time, patient age, diagnosis, anatomical lead target, device generation, or follow-up-duration data were available. No correction for multiple comparisons was applied because all inferential tests were exploratory; p values are therefore descriptive. Table 4 summarizes the exploratory statistical analyses.

Table 4
Exploratory statistical analyses of reporting and regulatory-record composition.

Analysis	Test	Statistic	p value	Effect size	Interpretation
Annual MAUDE event-type composition	Pearson chi-square test of independence	$\chi^2=991.6$; df = 20	< 0.001	Cramer's V = 0.112	Event-type composition varied by calendar year (small effect); describes reporting composition, not incidence.
Annual MAUDE report volume trend	Spearman rank correlation	$\rho = 0.196$	0.564	N/A	No statistically significant monotonic trend in total annual report volume.
Death-coded report proportion over time	Spearman correlation; grouped-binomial logistic model	$\rho=-0.782$; OR/year = 0.883 (95% CI 0.853–0.914)	Spearman p = 0.004; regression p < 0.001	OR per calendar year	Exploratory composition finding only; not evidence of mortality, survival, or device safety. Unadjusted, 11 annual observations.
Product-code reporting composition	Pearson chi-square test of independence	$\chi^2=1459.7$; df = 4	< 0.001	Cramer's V = 0.135	Varied by product code (small effect); not an indication-specific complication-rate comparison.
Manufacturer-associated reporting composition	Pearson chi-square test of independence	$\chi^2=4877.2$; df = 4	< 0.001	Cramer's V = 0.247	Composition varied across descriptive manufacturer-associated groups; not a manufacturer-safety comparison.
PMA lifecycle-domain composition	Pearson chi-square test of independence	$\chi^2=16.3$; df = 3	< 0.001	Cramer's V = 0.151	Lifecycle-domain composition differed pre-2015 vs. post-market window; small effect size.

2.10. Ethics and Data Availability

This study used publicly available FDA records and did not involve direct interaction with human participants, identifiable private information, or medical record review. Institutional review board approval was not required. Processed datasets, query manifests, validation definitions, code, and supplementary tables are intended for deposition in a public repository at submission.

3. Results

3.1. Integrated Dataset

The study integrated four FDA database layers, as summarized in Table 2 and Fig. 1. The MAUDE layer included 39,867 report-level records. The curated recall layer included 22 DBS-system recall events, corresponding to 24 product-level recall records. The PMA lifecycle layer included 716 curated movement-disorder DBS PMA/supplement records, of which 509 had decision dates within the 2015–2025 post-market reference window.

3.2. MAUDE Report Volume, Event Type, and Product-Code Distribution

The MAUDE extraction identified 39,867 report-level records. These comprised 20,494 malfunction reports (51.4%), 19,050 injury reports (47.8%), 321 death-coded reports (0.8%), and 2 reports classified as other. Annual report volumes varied over the study period, with 4,050 reports available for 2025 at the 14 June 2026 data lock. Because FDA reporting and public posting may be delayed, 2025 should not be interpreted as a fully mature surveillance year.

Figure 2 presents annual report counts, event-type proportions, and selected narrative-derived signal categories. Panels A and B summarize the MAUDE/openFDA dataset. Panel C shows dictionary-positive narrative categories by calendar year as a descriptive report-level plot, not as complication incidence. Full annual event-type counts are provided in Supplementary Table S1, and the figure-data table should be deposited with the public repository package.

Product-code distribution was highly concentrated in MHY, with 36,180 records (90.8%), followed by PJS with 1,975 records (5.0%) and NHL with 1,712 records (4.3%). No SGS-coded MAUDE/openFDA Device Event records were retrieved in the primary 2015–2025 extraction. This should not be interpreted as evidence that dystonia-related DBS complications were absent. More plausible explanations include lower dystonia DBS volume, reporting under broader Parkinsonian or tremor-related product codes, PMA-family coding that does not preserve indication specificity, and underreporting or coding variability for niche indications.

3.3. Validation-Informed MAUDE Narrative Signals

Manual validation showed substantial differences in reliability across narrative-derived categories. Infection/wound/erosion, explant/removal, hemorrhage/stroke-like event, and impedance/circuit problem were the strongest categories for main-text interpretation (Table 3). In the full MAUDE corpus, automated dictionary flags identified explant/removal in 10,583 reports (26.5%), infection/wound/erosion in 5,455 reports (13.7%), impedance/circuit problem in 6,554 reports (16.4%), and hemorrhage/stroke-like event in 1,504 reports (3.8%). Revision/reoperation (7,530 reports; 18.9%) and replacement/exchange (15,096 reports; 37.9%) were retained as cautious interpretive categories because their wording may overlap with explantation, exchange, staged management, or non-operative troubleshooting.

Manual validation materially affected interpretation. DBS adverse-event narratives often combine clinical events, troubleshooting details, suspected causes, concomitant components, and manufacturer assessments. Without validation, automated keyword counts may overstate component-specific problems. The final interpretation therefore weighted each narrative category according to its validation performance rather than treating all dictionary-derived flags as equivalent.

3.4. Exploratory Statistical Findings

After exclusion of sparse “Other” records, event-type composition differed across calendar years ($\chi^2=991.6$, $df = 20$, $p < 0.001$; Cramer’s $V = 0.112$), indicating statistically detectable but small reporting-composition heterogeneity (Table 4). Total annual report volume showed no statistically significant monotonic trend (Spearman $\rho = 0.196$, $p = 0.564$). Death-coded reports accounted for 0.8% of MAUDE records. Exploratory analysis of the annual death-coded report proportion suggested a decrease over calendar time (Spearman $\rho = -0.782$, $p = 0.004$; grouped-binomial OR per year = 0.883, 95% CI 0.853–0.914). This should not be interpreted as evidence of changing mortality, patient survival, or device safety. The model was unadjusted, used only 11 annual observations, and is vulnerable to changes in reporting practice, coding, denominator composition, and delayed posting, especially for 2025.

Event-type composition also differed by product code ($\chi^2=1459.7$, $df = 4$, $p < 0.001$; Cramer’s $V = 0.135$). Standardized residuals suggested relatively more injury-coded and fewer malfunction-coded NHL records, whereas PJS records showed relatively more malfunction-coded and fewer injury-coded reports; full residuals are provided in Supplementary Table S11. These residuals describe FDA event-type coding composition within reports. They should not be interpreted as indication-specific complication rates or comparative product safety. The two “Other” event-type records were excluded from chi-square testing because of extreme sparsity and were not merged with Injury, Malfunction, or Death categories.

Manufacturer-associated reporting composition differed across the three main manufacturer-associated groups ($\chi^2=4877.2$, $df = 4$, $p < 0.001$; Cramer’s $V = 0.247$). This result is reported only as reporting-composition heterogeneity. It does not compare manufacturer safety, device quality, clinical risk, or incidence, because installed base, product generations, indications, reporting workflows, exposure time, and denominator data are unavailable.

3.5. FDA Device Recall Layer

The recall extraction initially identified 70 raw records. After deduplication and manual curation, 24 product-level recall records were retained, corresponding to 22 unique DBS-system recall events. The retained events involved leads, extension/adaptor components, IPGs, chargers, programmer/software communication, MRI/labeling issues, and implantation accessories. Table 5 provides a condensed recall summary; full product-level and event-level records are presented in Supplementary Tables S5 and S6.

Table 5
Condensed summary of curated FDA Device Recall events involving DBS systems.

Manufacturer-associated group	Product code(s)	Recall events	Representative curated problem categories
Abbott/St. Jude-associated	LGW	1	MRI mode/controller communication issue
Abbott/St. Jude-associated	MHY	2	Directional lead material nonconformity; IPG communication failure
Boston Scientific-associated	NHL	4	Burr hole cover retaining clip/lead migration risk; extension kit labeling/use-by-date; IPG charging-related reset/transient therapy interruption; rechargeable IPG wire break/high impedance/loss of therapy
Medtronic-associated	LGW	1	Recharger first-use failure
Medtronic-associated	MHY	13	Clinician programmer software anomaly; connector plug labeling/use-by-date; extension tunneling accessory manufacturing issue; extension/impedance handling; IPG electronic vulnerability during cardioversion; IPG-programmer communication failure; lead insulation damage; lead kit labeling/use-by-date; lead placement accessory malfunction; MRI eligibility labeling/software issue; patient programmer connection anomaly; pocket adaptor conductor wire fracture; recharger unresponsive
Medtronic-associated	MHY; MRU	1	IPG-programmer communication failure

Recall records were treated as regulatory safety actions rather than clinical event counts. A single recall event may involve multiple products or corrective actions and cannot be converted into patient-level risk. Inclusion of accessory-related product codes in the recall layer reflects recall-record structure and does not alter the primary MAUDE product-code case definition.

3.6. FDA PMA and Supplement Lifecycle

The PMA extraction produced 1,648 raw records and 742 deduplicated PMA/supplement records. After manual curation, 716 records were retained as movement-disorder DBS PMA/supplement records. The principal PMA families were P960009, P140009, and P150031. Of the curated records, 509 had decision dates within 2015–2025.

PMA lifecycle activity was dominated by manufacturing/process/quality-system supplements, followed by design/component/material modifications and labeling/indications/instructions (Table 6). Within the 2015–2025 window, the corresponding counts were 381, 85, and 35 records, respectively. Figure 3 places the principal DBS PMA families within their regulatory lifecycle context.

Table 6
Curated PMA/supplement records by regulatory lifecycle domain.

Lifecycle domain	All available curated records	Records with decision date 2015–2025
Design / component / material modification	112	85
Labeling / indications / instructions	51	35
Manufacturing / process / quality system	530	381
Original approval / base PMA	3	2
Other regulatory supplement	2	0
Postapproval study protocol	7	4
Unspecified supplement reason	11	2

Comparison of collapsed PMA lifecycle-domain composition before 2015 versus 2015–2025 showed a statistically significant difference ($\chi^2=16.3$, $df = 3$, $p < 0.001$; Cramer's $V = 0.151$), consistent with a measurable but small-to-moderate shift in regulatory-record composition across lifecycle periods.

Manufacturing/process/quality-system supplements remained the dominant domain in both periods. Within 2015–2025, design/component/material modifications and labeling/indications/instructions represented clinically relevant regulatory-lifecycle domains, reflecting iterative hardware, software, labeling, and use-condition changes in mature DBS systems. PMA supplements are regulatory lifecycle records and should not be interpreted as adverse-event reports.

4. Discussion

4.1. Principal Findings

This multi-database FDA analysis describes DBS systems used for movement disorders through four public-record layers: MAUDE report-level safety signals, recall-level regulatory safety actions, PMA/supplement lifecycle activity, and FDA product-code definitions. The main findings are: (1) MAUDE/openFDA contained 39,867 report-level records for the primary product-code definition; (2) manual validation showed that only selected narrative-derived categories were reliable enough for main-text interpretation; (3) recall analysis identified 22 curated DBS-system recall events; (4) PMA analysis identified 716 curated DBS PMA/supplement lifecycle records; and (5) exploratory statistical tests demonstrated reporting-composition heterogeneity across calendar years, product codes, manufacturer-associated groups, and PMA lifecycle periods.

The exploratory inferential analyses quantify differences in record composition, but they do not convert passive surveillance reports into epidemiological rates. These tests should be read as structured descriptions of heterogeneity within public FDA records, not as causal, comparative, or incidence-based inference.

4.2. Relation to Prior MAUDE-Based DBS Studies

Prior DBS MAUDE studies have usually examined a single database layer and a specific clinical or device context, including Parkinson's disease complications, parkinsonian symptoms without tremor, electromagnetic interference, or DBS for refractory obsessive-compulsive disorder [21–24]. The present analysis differs from that work in several respects. Its case definition rests on regulatory product codes rather than on trade names alone. It integrates MAUDE, recall, PMA/supplement, and product-classification records while preserving the interpretive unit of each database. Candidate narrative categories are also validated before the signals used in the main text are selected. This approach cannot overcome the limitations of passive surveillance, but it reduces the risk that raw keyword counts will be mistaken for clinically adjudicated complications.

4.3. Device-Level Interpretation of MAUDE Signals

The validated narrative categories are clinically and technically plausible and correspond to recognizable DBS problem domains, but they were not validated against patient-level clinical outcomes. Infection/wound/erosion is directly relevant to implanted cranial hardware and to the device-tissue interface at the burr-hole fixation site, along the extension tract, and over the IPG pocket, where soft-tissue thickness, component profile, and material surface properties interact with wound integrity and with the risk of partial or complete system explantation [11, 14, 16]. Hemorrhage/stroke-like narratives overlap with known intracranial bleeding risks in DBS surgery, although MAUDE narratives cannot reliably distinguish perioperative hemorrhage, delayed events, unrelated cerebrovascular disease, or coding ambiguity [12]. Impedance/circuit-problem reports are consistent with the hardware-failure and system-integrity domains described in the DBS clinical and technical complication literature [11, 15]. In device terms, out-of-range or drifting impedance is the principal accessible indicator of conductor, insulation, and connector integrity. It may reflect conductor fatigue fracture under cyclic cervical loading, insulation abrasion or breach, connector corrosion or incomplete seating, or change at the electrode-tissue interface. Public narratives rarely permit these mechanisms to be distinguished from one another, which limits the mechanistic resolution obtainable from MAUDE. Reports of this type may also be overrepresented in MAUDE because objective electrical measurements are more reportable than subjective symptom changes. Explant/removal narratives indicate clinically meaningful system discontinuation, but they do not establish indication, timing, causality, or preventability.

These categories should therefore be read as report-level signals. MAUDE narratives do not provide standardized clinical adjudication, denominator data, or follow-up. A report describing explantation may not clarify whether explantation was related to infection, erosion, pain, loss of efficacy, patient preference, surgical strategy, or unrelated clinical circumstances. Trial-level and cohort-level evidence, including recent meta-analytic synthesis in Parkinson's disease DBS [17], addresses clinical efficacy and adjudicated safety under conditions that differ fundamentally from public adverse-event reporting. The present study complements clinical series, trials, and registries; it does not replace them.

4.4. Product-Code and Manufacturer-Associated Composition

Product-code composition was highly uneven, with MHY dominating the MAUDE dataset. The product-code event-type chi-square test showed statistically significant reporting-composition heterogeneity, although the effect size was small. Product codes do not map cleanly onto individual indications, surgical targets, patient populations, or device generations. SGS illustrates this limitation: the absence of SGS-coded MAUDE records does not imply the absence of dystonia-related events, but rather the limits of product-code-based surveillance for niche indications.

Manufacturer-associated reporting composition also differed statistically. This finding is expected in a heterogeneous device field with different installed bases, product generations, regulatory histories, reporting practices, and PMA-family structures. The manufacturer-associated analysis was included to describe reporting composition, not to rank manufacturers. Without denominator data, implant volume, product-generation exposure, indication mix, and standardized clinical adjudication, manufacturer-associated comparisons cannot estimate comparative safety.

4.5. Recall and PMA Layers as Device-Lifecycle Context

Recall and PMA records add regulatory context that MAUDE alone cannot provide. Recall events identify issues that reached a regulatory safety-action threshold [30], whereas PMA and supplement records document lifecycle changes in Class III device families [31–33]. In this study, recall events involved clinically and technically meaningful DBS system domains, including leads, extension/adaptor components, IPGs, chargers, programmer/software communication, MRI/labeling, and implantation accessories. PMA activity was dominated by manufacturing/process/quality-system records, as expected for mature device families, but these records should not be read as a clinical complication distribution.

The PMA lifecycle findings place MAUDE and recall records in a broader regulatory context. DBS systems represented in public adverse-event data are not static products. Over time, they undergo changes in hardware, software, labeling, manufacturing processes, accessories, MRI-conditional use instructions, and quality-system documentation. The predominance of manufacturing/process/quality-system supplements reflects routine regulatory maintenance of mature implantable systems. Design/component/material and labeling supplements likely reflect technology evolution, including rechargeable IPGs, sensing-capable systems, software interfaces, accessory changes, and MRI-related labeling. These PMA records document regulatory lifecycle activity; they are not adverse-event counts and do not constitute evidence of clinical harm.

4.6. Implications for Device Surveillance and Design Feedback

This analysis shows that public FDA datasets can support device-level neuromodulation surveillance research when their limitations are handled explicitly. The product-code case definition improves specificity. Manual validation reduces the risk of overinterpreting keyword-derived narrative categories. Recall curation limits false-positive retrieval from ambiguous terms. PMA lifecycle analysis adds regulatory and engineering context without conflating approval or supplement activity with clinical adverse events.

The central methodological implication is that FDA public-record databases must be interpreted on their own terms. MAUDE, recall, PMA, and product-classification records answer different questions. Their synthesis is useful when it remains descriptive and triangulated rather than causal.

The three evidentiary layers together describe a partial feedback path from field performance to device design. Recall events in this dataset involved the same physical subsystems that dominate the validated MAUDE categories, namely leads and extensions, connector and adaptor components, IPGs and their power and charging subsystems, and programmer software and communication links. The design/component/material domain of the PMA supplement record shows where manufacturers subsequently intervened in mature product families. Public records cannot demonstrate that a given supplement resolved a given failure mode, and the causal chain from report to design change is not recoverable from these data. They do, however,

indicate which subsystems generate persistent field signal in long-dwelling implantable neurostimulation systems, and where component-level traceability through unique device identification would most improve post-market engineering feedback [34, 35].

4.7. Strengths and Limitations

The strengths of this study include a regulatory product-code case definition, integration of multiple FDA database layers, manual validation of a 400-report MAUDE sample against predefined category definitions, recall/PMA curation, and explicit preservation of database-specific interpretive limits. The main limitation is that all findings remain public-record and report-level observations.

The limitations are substantial. MAUDE is a passive surveillance system affected by underreporting, duplicate or incomplete reporting, reporting delays, manufacturer-specific workflows, variable narrative quality, and absence of denominator data. It cannot estimate incidence, patient-level risk, mortality, complication rates, comparative manufacturer safety, or causality. The study had no access to implant counts, exposure time, patient age, diagnosis, lead target, disease severity, programming history, device generation, or follow-up duration; consequently, multivariable adjustment for clinical confounding was not possible. Deduplication was report-level rather than patient-level. The validation reference sample was manually adjudicated, but a retained pre-consensus two-reviewer matrix was unavailable; kappa values therefore assess automated category performance against manual reference labels rather than human inter-rater reliability. The PMA lifecycle taxonomy was author-derived and descriptive. Manufacturer-associated harmonization was necessary but partly brand-informed and cannot support comparative safety claims. Statistical tests were exploratory, unadjusted for multiple comparisons, and sensitive to large sample size. Data from 2025 require particular caution because public posting and manufacturer reporting delays may make the most recent year less mature than earlier years.

4.8. Future Directions

Future DBS surveillance research should link public FDA data with institutional surgical registries, prospective cohorts, and UDI/GUDID-informed device mapping. UDI/GUDID linkage may improve component-level traceability, although implementation and completeness vary across the 2015–2025 window and cannot retrospectively resolve all historical reporting ambiguities. International regulatory systems, including EUDAMED in Europe, may eventually provide complementary post-market surveillance context, but database structure, public access, and reporting rules differ from FDA systems. Narrative classification could be improved with validated natural-language processing pipelines, provided that such models are trained and tested against expert-adjudicated reference sets rather than deployed as unvalidated keyword expansion.

5. Conclusions

This multi-database FDA analysis provides a structured, device-level public-record account of implanted DBS systems used in movement disorders. MAUDE/openFDA records characterized report-level signals of hardware and system-integrity problems, FDA Device Recall records identified regulatory safety actions spanning leads, extension and adaptor components, IPGs, chargers, programmer software, and labeling, and PMA/supplement records reconstructed the regulatory lifecycle of the principal DBS system families, including their design, component, and material modifications. Manual validation showed that narrative-derived MAUDE categories

varied substantially in reliability. Infection/wound/erosion, explant/removal, hemorrhage/stroke-like event, and impedance/circuit problem were the categories best supported for main interpretation.

Exploratory statistical analyses showed heterogeneity in reporting composition across calendar year, product code, manufacturer-associated group, and PMA lifecycle period. These analyses add a limited inferential layer but do not estimate epidemiological rates or causal effects. Public FDA records should therefore be used as hypothesis-generating and regulatory-context resources, not as substitutes for clinical registries, adjudicated safety studies, or prospective follow-up.

Abbreviations

CI

confidence interval

DBS

deep brain stimulation

df

degrees of freedom

EUDAMED

European Database on Medical Devices

F1

harmonic mean of precision and sensitivity

FDA

United States Food and Drug Administration

GPI

globus pallidus internus

GUDID

Global Unique Device Identification Database

IPG

implantable pulse generator

JSON

JavaScript Object Notation

LGW

FDA product code retained in recall–layer curation when linked to DBS systems

MAUDE

Manufacturer and User Facility Device Experience

MDR

Medical Device Report

MHY

FDA product code for implanted electrical stimulator for parkinsonian tremor

MRI

magnetic resonance imaging

MRU

FDA product code retained in recall–layer curation when linked to DBS systems

NHL

FDA product code for implanted electrical stimulator for parkinsonian symptoms

OLM

FDA product code for deep brain stimulator for obsessive–compulsive disorder

openFDA

FDA open data platform

OR

odds ratio

PJS

FDA product code for implanted electrical stimulator for essential tremor

PMA

premarket approval

PPV

positive predictive value

RECORD

REporting of studies Conducted using Observational Routinely collected health Data

SGS

FDA product code for deep brain stimulation for the treatment of dystonia

STN

subthalamic nucleus

STROBE

Strengthening the Reporting of Observational Studies in Epidemiology

UDI

unique device identifier

Declarations

Supplementary Materials

The following supporting information is intended for submission with the manuscript: Table S1: annual MAUDE event-type counts; Table S2: manufacturer-associated distribution; Table S3: full validation metrics for all narrative-derived categories; Table S4: automated component-category assignments; Table S5: curated recall product-level records; Table S6: curated recall event-level records; Table S7: PMA manufacturer summary; Table S8: PMA product-code summary; Table S9: PMA annual counts; Table S10: product-code retrieval and query-manifest summary; Table S11: exploratory statistical-analysis details and standardized residuals. A completed RECORD reporting checklist is provided as a separate supplementary file.

Statements and Declarations

Funding

This research received no external funding.

Competing Interests

The authors have no competing interests to declare that are relevant to the content of this article.

Author Contributions

Conceptualization: J.W., A.B.M. and W.W.; methodology: J.W., A.B.M., P.J.W. and W.W.; software and data retrieval: J.W.; validation: J.W. and A.B.M.; formal analysis: J.W., A.B.M. and O.L.; data curation: J.W., O.L. and A.B.M.; investigation and clinical interpretation: J.W., A.B.M., O.L., P.J.W. and W.W.; original draft preparation: J.W.; review and editing: all authors; supervision: J.W. and W.W.; project administration: J.W. and A.B.M. All authors have read and agreed to the submitted version of the manuscript and meet the ICMJE authorship criteria.

Ethics Approval

Not applicable. This study used publicly available, de-identified FDA records and did not involve direct interaction with human participants, identifiable private information, or medical record review. Institutional review board approval was therefore not required.

Consent to Participate and Consent for Publication

Not applicable. The study did not involve human participants, identifiable individual data, or any material requiring participant consent for publication.

Data Availability

Raw data were obtained from public FDA data sources. The supplementary workbook accompanying this submission (Supplementary_Tables.xlsx) contains processed summary tables, validation metrics, query and curation notes, and exploratory statistical details. Because raw FDA exports may be large and are publicly reproducible, repository deposition may use query manifests, retrieval scripts, and processed analysis tables rather than duplicating all raw public files.

Use of Generative AI and AI-Assisted Technologies

AI-assisted tools, including Grammarly and DeepL, were used for language editing only. They were not used as authors or as scientific adjudicators. Manual validation and consensus adjudication of MAUDE narratives were performed by human clinical reviewers from the author group. All scientific content, data interpretation, methodological decisions, validation definitions, and final responsibility remain with the authors.

References

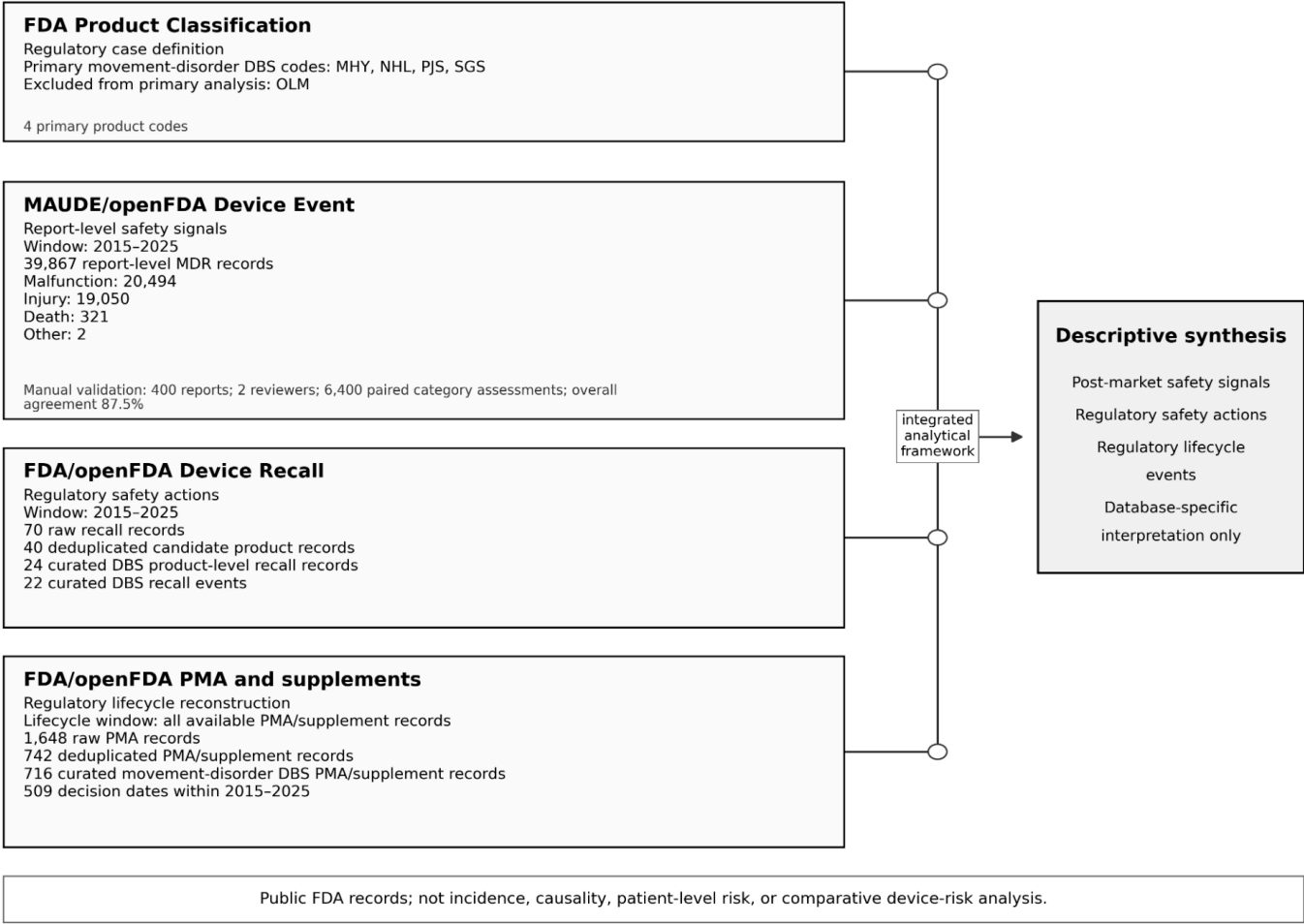
1. S. Krishnan, K.K. Pisharady, K.P. Divya et al., Deep brain stimulation for movement disorders. *Neurol. India*. **66**(Suppl), S90–S101 (2018)
2. A. Rughani, J.M. Schwalb, C. Sidiropoulos et al., Congress of Neurological Surgeons systematic review and evidence-based guideline on subthalamic nucleus and globus pallidus internus deep brain stimulation for the treatment of patients with Parkinson's disease: executive summary. *Neurosurgery*. **82**(6), 753–756 (2018)

3. M. Zappia, A. Albanese, E. Bruno et al., Treatment of essential tremor: a systematic review of evidence and recommendations from the Italian Movement Disorders Association. *J. Neurol.* **260**(3), 714–740 (2013)
4. F.B. Rodrigues, G.S. Duarte, D. Prescott et al., Deep brain stimulation for dystonia. *Cochrane Database Syst. Rev.* **1**(1), CD012405 (2019)
5. F.M. Weaver, K. Follett, M. Stern et al., Bilateral deep brain stimulation vs best medical therapy for patients with advanced Parkinson disease: a randomized controlled trial. *JAMA* **301**(1), 63–73 (2009)
6. A. Kupsch, R. Benecke, J. Müller et al., Pallidal deep-brain stimulation in primary generalized or segmental dystonia. *N Engl. J. Med.* **355**(19), 1978–1990 (2006)
7. M.T. Barbe, P. Reker, S. Hamacher et al., DBS of the PSA and the VIM in essential tremor: a randomized, double-blind, crossover trial. *Neurology.* **91**(6), e543–e550 (2018)
8. S. Bratsos, D. Karponis, S.N. Saleh, Efficacy and safety of deep brain stimulation in the treatment of Parkinson's disease: a systematic review and meta-analysis of randomized controlled trials. *Cureus* **10**(10), e3474 (2018)
9. A. Fasano, A.M. Lozano, Deep brain stimulation for movement disorders: 2015 and beyond. *Curr. Opin. Neurol.* **28**(4), 423–436 (2015)
10. W.J. Neumann, R.S. Turner, B. Blankertz et al., Toward electrophysiology-based intelligent adaptive deep brain stimulation for movement disorders. *Neurotherapeutics.* **16**(1), 105–118 (2019)
11. D.M. Patel, H.C. Walker, R. Brooks et al., Adverse events associated with deep brain stimulation for movement disorders: analysis of 510 consecutive cases. *Neurosurgery.* **11**(Suppl 2), 190–199 (2015)
12. J. Tiefenbach, L. Favi Bocca, O. Hogue et al., Intracranial bleeding in deep brain stimulation surgery: a systematic review and meta-analysis. *Stereotact. Funct. Neurosurg.* **101**(3), 207–216 (2023)
13. A.J. Bullard, B.C. Hutchison, J. Lee et al., Estimating risk for future intracranial, fully implanted, modular neuroprosthetic systems: a systematic review of hardware complications in clinical deep brain stimulation and experimental human intracortical arrays. *Neuromodulation.* **23**(4), 411–426 (2020)
14. P.K. Doshi, N. Rai, D. Das, Surgical and hardware complications of deep brain stimulation—a single surgeon experience of 519 cases over 20 years. *Neuromodulation.* **25**(6), 895–903 (2022)
15. A.M. Cabral, A.A. Pereira, M.F. Vieira et al., Prevalence of distinct types of hardware failures related to deep brain stimulation. *Neurosurg. Rev.* **45**(2), 1123–1134 (2022)
16. van I. Kroonenburgh, S.K.H. Tan, P. Heiden et al., Incidence and management of hardware-related wound infections in spinal cord, peripheral nerve field, and deep brain stimulation surgery: a single-center study. *Stereotact. Funct. Neurosurg.* **102**(1), 13–23 (2024)
17. J.J. Petersen, C.B. Kamp, P. Faltermeier et al., Deep brain stimulation for Parkinson's disease: systematic review with meta-analysis and trial sequential analysis. *BMJ Med.* **3**(1), e000705 (2024)
18. U.S. Food and Drug Administration: Device adverse event overview. openFDA. <https://open.fda.gov/apis/device/event/> (2026). Accessed 14 June 2026
19. U.S. Food and Drug Administration: Manufacturer and User Facility Device Experience (MAUDE). openFDA. <https://open.fda.gov/data/maude/> (2026). Accessed 14 June 2026
20. U.S. Food and Drug Administration: About Manufacturer and User Facility Device Experience (MAUDE) database. <https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers->

- importers-and-device-user-facilities/about-manufacturer-and-user-facility-device-experience-maude-database (2026). Accessed 14 June 2026
21. M. Ward, M. Ahmed, C. Markosian et al., Complications associated with deep brain stimulation for Parkinson's disease: a MAUDE study. *Br. J. Neurosurg.* **35**(5), 625–628 (2021)
 22. J. Bennett, J. MacGuire, E. Novakovic et al., Characterizing complications of deep brain stimulation devices for the treatment of parkinsonian symptoms without tremor: a federal MAUDE database analysis. *Cureus* **13**(6), e15539 (2021)
 23. S. Rahimpour, M. Kiyani, S.E. Hodges et al., Deep brain stimulation and electromagnetic interference. *Clin. Neurol. Neurosurg.* **203**, 106577 (2021)
 24. M.H. Porwal, H. Karra, U. Sharma et al., Deep brain stimulation for refractory obsessive-compulsive disorder: a review and analysis of the FDA MAUDE database. *Surg. Neurol. Int.* **13**, 399 (2022)
 25. E.I. Benchimol, L. Smeeth, A. Guttman et al., The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) statement. *PLoS Med.* **12**(10), e1001885 (2015)
 26. U.S. Food and Drug Administration: Product classification MHY: stimulator, electrical, implanted, for parkinsonian tremor. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=MHY> (2026). Accessed 14 June 2026
 27. U.S. Food and Drug Administration: Product classification NHL: stimulator, electrical, implanted, for parkinsonian symptoms. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=NHL> (2026). Accessed 14 June 2026
 28. U.S. Food and Drug Administration: Product classification PJS: stimulator, electrical, implanted, for essential tremor. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=PJS> (2026). Accessed 14 June 2026
 29. U.S. Food and Drug Administration: Product classification SGS: deep brain stimulation for the treatment of dystonia. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=SGS> (2026). Accessed 14 June 2026
 30. U.S. Food and Drug Administration: Device recall overview. openFDA. <https://open.fda.gov/apis/device/recall/> (2026). Accessed 14 June 2026
 31. U.S. Food and Drug Administration: Device pre-market approval overview. openFDA. <https://open.fda.gov/apis/device/pma/> (2026). Accessed 14 June 2026
 32. T. Marjenin, P. Scott, A. Bajaj et al., FDA perspectives on the regulation of neuromodulation devices. *Neuromodulation.* **23**(1), 3–9 (2020)
 33. C. Peña, K. Bowsher, A. Costello et al., An overview of FDA medical device regulation as it relates to deep brain stimulation devices. *IEEE Trans. Neural Syst. Rehabil Eng.* **15**(3), 421–424 (2007)
 34. F. Tettey, S.K. Parupelli, S. Desai, A review of biomedical devices: classification, regulatory guidelines, human factors, software as a medical device, and cybersecurity. *Biomed. Mater. Devices.* **2**(1), 316–341 (2024). <https://doi.org/10.1007/s44174-023-00113-9>
 35. S.J. Mulla, M. Patel, Global regulatory perspectives on sensor-enabled and biomaterial-integrated medical devices: a focus on India, Canada, and Australia. *Biomed. Mater. Devices.* **4**(2), 1303–1324 (2026). <https://doi.org/10.1007/s44174-025-00327-z>

Figures

FDA multi-database analytical framework for DBS in movement disorders

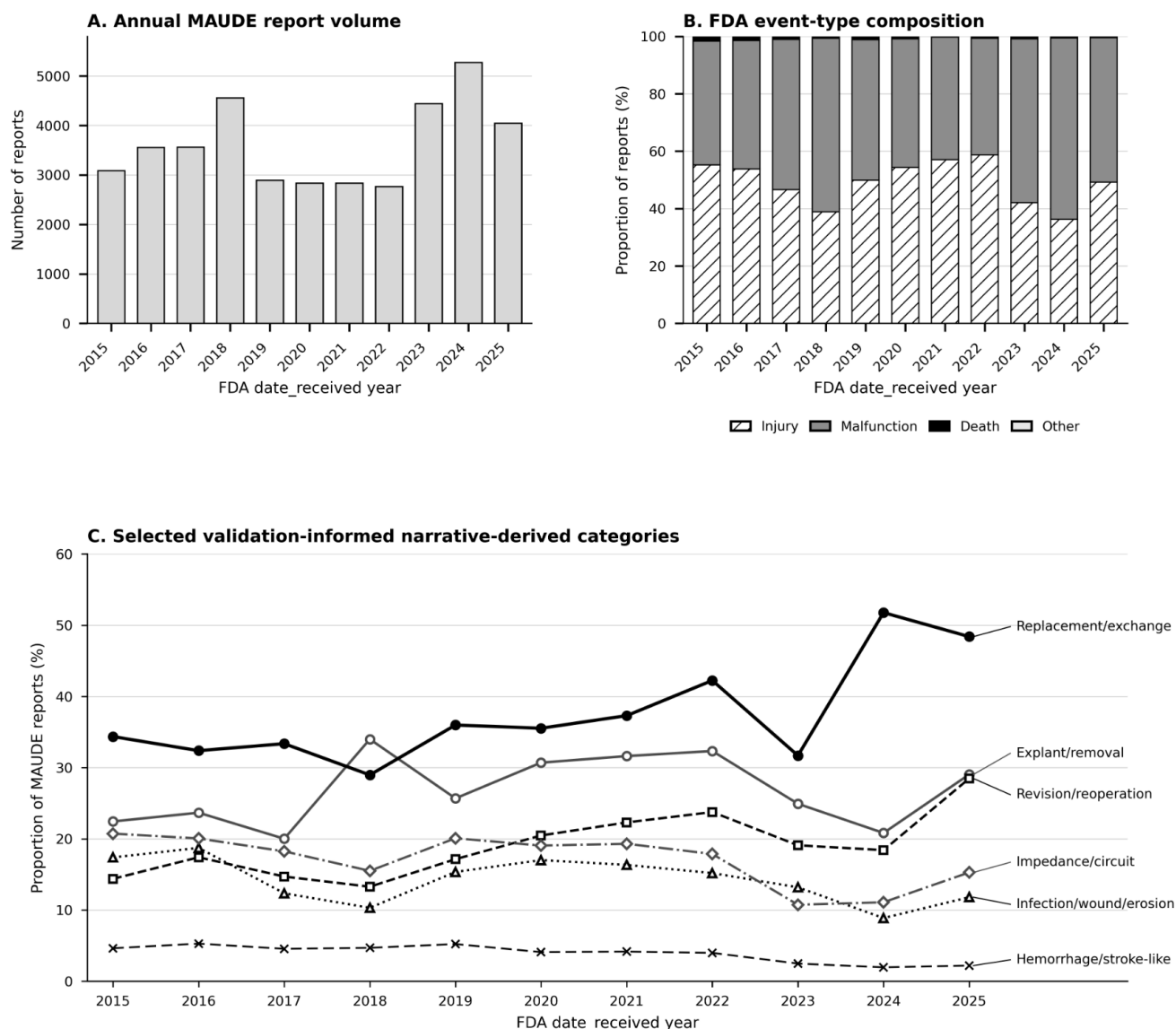


Abbreviations: DBS, deep brain stimulation; FDA, United States Food and Drug Administration; MAUDE, Manufacturer and User Facility Device Experience; MDR, Medical Device Report; OLM, obsessive-compulsive disorder DBS product code excluded from primary movement-disorder analysis; PMA, premarket approval.

Figure 1

FDA multi-database analytical framework for DBS in movement disorders. The workflow shows four FDA data layers, namely Product Classification, MAUDE/openFDA Device Event, FDA Device Recall, and FDA PMA/supplements, feeding into database-specific curation and conservative synthesis. The figure is a conceptual workflow diagram rather than a data-derived results plot. It should not be read as an incidence estimate, patient-level risk model, manufacturer-comparative safety analysis, or causal analysis. Abbreviations: DBS, deep brain stimulation; FDA, United States Food and Drug Administration; MAUDE, Manufacturer and User Facility Device Experience; PMA, premarket approval.

MAUDE/openFDA Device Event reports involving DBS movement-disorder systems, 2015-2025



Percentages represent proportions among MAUDE reports in each calendar year, not complication incidence. Reporting period is based on FDA date_received, not clinical event date.

Abbreviations: DBS, deep brain stimulation; FDA, United States Food and Drug Administration; MAUDE, Manufacturer and User Facility Device Experience.

Figure 2

Annual MAUDE/openFDA Device Event reports and selected narrative-derived signal categories, 2015–2025. Panel A: annual number of MAUDE reports. Panel B: stacked annual proportions of FDA event types. Panel C: line plot of selected dictionary-positive narrative categories. Values are report-level counts or proportions among MAUDE reports received in each calendar year. They should not be interpreted as incidence, patient-level risk, manufacturer-comparative safety, or causal effects. The reporting period is based on FDA

date_received, not clinical event date. Abbreviations: DBS, deep brain stimulation; FDA, United States Food and Drug Administration; MAUDE, Manufacturer and User Facility Device Experience.

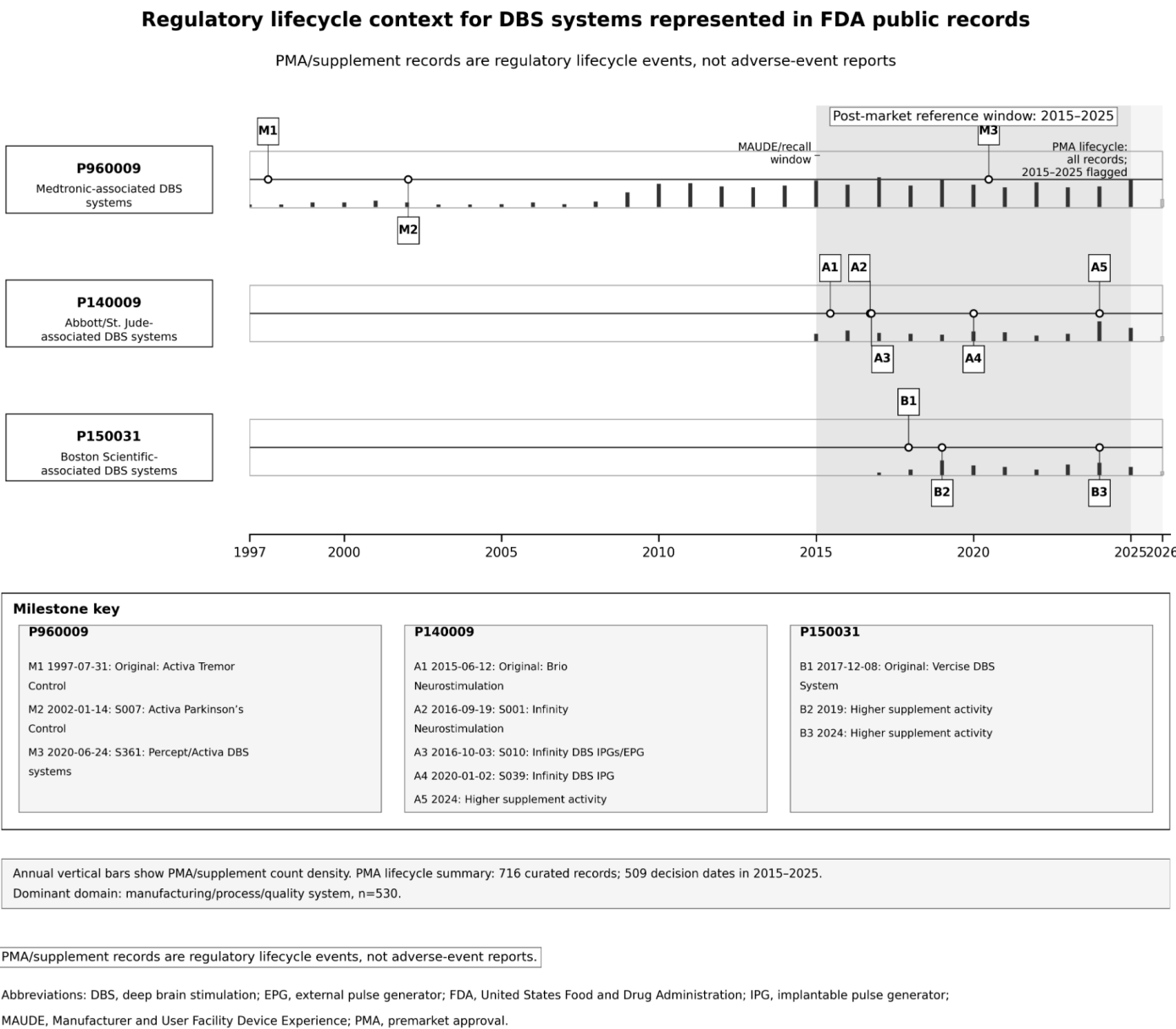


Figure 3

Regulatory lifecycle context for DBS systems represented in FDA public records. This schematic, data-informed timeline shows PMA families P960009, P140009, and P150031, highlighting the 2015–2025 post-market surveillance window and ongoing supplement activity. It is intended to contextualize regulatory lifecycle activity. It should not be interpreted as incidence, patient-level risk, manufacturer-comparative safety, or causal inference. Abbreviations: DBS, deep brain stimulation; FDA, United States Food and Drug Administration; PMA, premarket approval.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [RECORDChecklist.docx](#)
- [SupplementaryTables.xlsx](#)
- [SupplementaryTables.xlsx](#)