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Life extension without disclosed testing: a model-level verification audit of FDA-cleared remanufactured da Vinci instruments, 2022– 2026

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Abstract

Purpose

The US Food and Drug Administration (FDA) has cleared remanufactured da Vinci instruments for additional clinical uses since 2022. We assessed whether surgical teams can verify, from public records, each model's intended lifetime, the testing behind its added uses, and its identity in adverse-event reports.

Methods

Cross-sectional audit of all eight 510(k) clearances under product code QSM (nine models) through 22 October 2026. Each 510(k) summary was coded across ten validation domains (90 cells) and linked to dated original equipment manufacturer (OEM) policy-page versions, securities filings, court records, and FDA adverse-event reports. Two coding passes were compared and adjudicated against source documents.

Results

Every numeric life-extension claim (ten added uses; four models) applied to a monopolar energy instrument, yet no summary reported a test sample size, cycle exposure, acceptance criterion, or electrical-safety result, and none unambiguously stated the original labeled use count. Six of eight clearances cited another clearance for their test methods, leaving three evidence lineages. The OEM first listed cleared models in a page version dated March 2025, 897 days after the first clearance. All 26 identified adverse-event reports concerned scissors; 23 were filed by the OEM about a competitor's product, 23 carried the OEM product code, and one carried a cohort model number.

Conclusion

Public records confirm which remanufactured instruments are cleared but not how far their life has been tested or which device a failure report concerns. A ten-item model-level verification record would support procurement, point-of-use review, and surveillance.

Introduction

Da Vinci EndoWrist instruments are reusable but carry a procedure limit set by the original equipment manufacturer (OEM) and enforced by an on-instrument use counter. Independent firms now remanufacture selected instruments for additional clinical use. FDA treats processing as remanufacturing when it significantly changes a finished device's performance or safety specifications, and a 510(k) clearance indicates substantial equivalence to a predicate; the public summary is not the

full submission [1]. Since 2022, FDA has cleared remanufactured da Vinci instruments under product code QSM [2].

For robotic surgeons the question is concrete: can the next instrument loaded onto the robot be verified for the use it is about to perform? The question matters most for monopolar instruments. Monopolar curved scissors are the instrument most often exchanged prematurely during robotic cases [3] and are prominent in device-related injury reports [4], and insulation failure of monopolar instruments can cause stray-energy burns and vascular injury [5–7]. An added-use claim for an energy instrument is therefore a claim about electrical integrity late in an extended life.

Prior work addresses original instrument life [3], the environmental cost of robotic surgery [8, 9], and repair rights for medical devices [10]. Regulatory studies show that 510(k) claims propagate through predicate networks [11–13], and robotic surveillance studies describe instrument malfunction, including arcing, as the dominant report type [4, 14]. We found no published evaluation of a QSM-cleared remanufactured instrument and no study linking what such clearances disclose to what a surgical team can verify at the point of use.

We therefore audited the public record as a verification chain with four links: the cleared model must be identifiable, the testing behind its added life must be interpretable, the OEM guidance on which hospitals rely must reflect the clearance, and a failure must be attributable to the remanufactured device. The aim is practical: to show surgeons, sterile-processing teams, and value-analysis committees what they can confirm before a remanufactured instrument is used, and what they must request from the remanufacturer. The study evaluates public verifiability, not confidential submissions, comparative safety, or the merits of litigation.

Methods

Design, sources, and cutoff

This cross-sectional documentary audit examined US regulatory, corporate, court, and surveillance records with an evidence cutoff of 22 October 2026; retrieval, coding, and status checks were completed on 23 October 2026. The unit of analysis was the clearance-model pair; clearance-level results are reported separately because K252926 covers two models. Record flow is shown in Online Resource 1.

Regulatory cohort

Eligible records were 510(k) clearances under product code QSM for remanufactured da Vinci instruments. We searched openFDA [15], FDA's downloadable 510(k) file [2], and FDA's live 510(k) database, and retrieved each decision letter, indications-for-use form, and 510(k) summary [16–23], rendering image-only pages for visual review. The downloadable file contained decisions through 18 October 2026; a live database query on 23 October 2026 returned the same eight records, with no

decision dated 19–22 October. We recorded applicant, receipt and decision dates, platform, predicate, methods references, standards, and statements about original or additional uses.

Disclosure coding

Each of nine models was coded across ten domains, yielding 90 model-domain cells. “Specific” required a domain-relevant test, evaluation, or claim; umbrella phrases such as “validation of reprocessing” were coded “generic.” We recorded methods level (none, named, described, or protocol-level), cited standards or guidance, test sample or cycle exposure, labeled additional-use claims, acceptance criteria, numeric results, and applicability. Additional-use claims were not treated as test exposure. A sensitivity rule counted generic mentions. From these codes we derived, for each clearance, the items a hospital could verify from public sources. The codebook, coded data, and adjudication log are in Online Resource 2 and in a public repository [24].

Evidence lineage

An evidence lineage comprised clearances that explicitly cited another 510(k) as the reference for test or reprocessing methods; a clearance citing no 510(k) for methods was a lineage root. Predicates were recorded separately because a predicate supports substantial equivalence rather than a test method.

OEM information channel

We read the OEM’s clinician-facing instrument-policy page [25] live and in 21 Internet Archive captures from 2022 to 2026, including 11 distinct captures spanning February–November 2025. Versions were dated by the page’s stated “as of” date and by their first archived observation. The listing interval was the time from FDA decision to the first version naming the clearance, reported to both dates. We also searched the OEM’s annual and quarterly securities filings from 2023 to 2026 [26].

Litigation and device-event linkage

Five litigation families were identified from securities filings, CourtListener, and docket searches [27–31]. Orders, pleadings, exhibits, and disclosures were coded as dated events, labeled by evidentiary status (agency communication, party allegation or position, judicial account or holding, docket event, or reported settlement), and linked to devices as exact by name, exact by unique inference, family, or platform. Party allegations and settlement terms were not treated as adjudicated facts.

Postmarket identity

We queried openFDA’s Manufacturer and User Facility Device Experience (MAUDE) endpoint [15] with nine searches: product code QSM; cohort applicant names in manufacturer fields and narratives;

“remanufactured EndoWrist” as brand; and narratives combining “remanufactured” with “EndoWrist.” The deduplicated union was reviewed. Searches by cohort model number could not separate remanufactured from OEM instruments because model numbers are shared. We recorded reporter type, product code, model number, manufacturer field, problem, and patient outcome. MAUDE reports are unverified and lack an exposure denominator; we report counts, not rates.

Literature context

Two PubMed strategies through the cutoff returned 406 unique records; Europe PMC translations and 57 non-PubMed preprints were also screened.

Coding and adjudication

L.G. performed the initial source extraction and coding with assistance from a large language model, then conducted a second, label-blind coding pass; S.P. reviewed the completed coding and adjudicated discrepancies. Both passes covered 90 model-domain cells, 33 device-event links, and 47 event-status records. Agreement was summarized with Cohen’s kappa [32] and, for the ordinal methods-level code, quadratic weighted kappa [33]; these values describe agreement between the two model-assisted passes, not human inter-rater reliability. All discordant codes were adjudicated by the senior author against the source documents, and decisions are recorded in Online Resource 2.

Analysis

Analyses were descriptive (counts, proportions, medians, and ranges). No hypothesis tests were performed. Non-reporting in a public summary was not interpreted as absence from the confidential submission.

Results

Cohort

The cohort comprised eight clearances and nine models from three applicant entities, with decisions from 30 September 2022 to 26 March 2026; five decisions occurred in 2025 (Table 1). Five models were Rebotix grasping instruments for the da Vinci S/Si, and four were monopolar energy instruments: two Iconocare curved scissors (Si and X/Xi) and a Restore cautery hook and spatula (X/Xi). FDA registration listed the three Iconocare and Restore clearances under Restore Robotics Repairs LLC, and Restore’s pleadings describe Iconocare as its subsidiary [31], a party allegation rather than an adjudicated relationship. Every remanufactured model retained its OEM model number. Median receipt-to-decision time was 188.5 days (range 133–588), and every primary predicate was an OEM da Vinci instrument or system.

What the summaries disclose

Across 90 cells, 44 (49%) specifically named a domain, 15 (17%) used only a generic phrase, and 31 (34%) made no mention (Fig. 1; Table 2). Methods were named in 40 cells and described in 3, and 19 cells across six clearances cited a consensus standard or FDA guidance. No cell reported a test sample size, test-cycle exposure, acceptance criterion, or numeric result. Electrical safety testing was named in all eight clearances and six cited IEC 60601-1, but no summary reported a dielectric, insulation, or leakage-current limit or result. Cleaning was specifically addressed in K242610 and K252926 without residue limits or results; sterilization appeared only as a generic reprocessing phrase; and no summary described remanufacturer-specific labeling or traceability. Under the permissive rule, 59 of 90 cells contained some mention.

Life-extension claims

Every numeric life-extension claim in the cohort applied to a monopolar energy instrument. K210478, K242610, and K252926 (four models, all monopolar) each claimed ten additional uses, whereas the five Rebotix grasper summaries stated only that the counter had been reset to permit an “additional controlled set of uses,” without a number or reset method. No summary unambiguously stated the OEM-labeled use count, and K242610 described ten cycles both as its indicated use life and as additional uses. If the OEM limit is the commonly reported ten uses [3, 29], the numeric claims would double an energy instrument’s labeled life, but no summary reported how many instruments, cycles, or electrical tests supported the added uses. A hospital could therefore verify the model, platform, and regulatory status of every cleared instrument, but not its total intended lifetime or any test limit (Table 3).

Evidence inheritance

Six of eight clearances cited another 510(k) as their methods reference (Fig. 2a). Four later Rebotix summaries cited K241872 and repeated substantially similar testing language; K242610 cited K210478; and K252926 cited K203632, an OEM reusable-instrument clearance, for the validated cleaning and reprocessing methods associated with its ten additional uses. The eight clearances therefore rested on three stated methods lineages rather than eight independent narratives. This documents reliance in public summaries; it does not establish that the underlying submissions lacked additional data.

OEM clinician-facing information

The OEM policy page carried no remanufacturing statement in an August 2022 capture. A version dated 1 March 2023 stated that the OEM was unaware of a clearance for its fourth-generation systems but named no model, and it remained on display in captures through 16 March 2025. A version dated 15 March 2025, first observed on 16 April 2025, listed K210478, K241872, and K242610; a version dated 22

September 2025 added the four August 2025 clearances; and the K252926 models appeared in a version dated 1 April 2026. Listing intervals to the stated date were 897 days for K210478, 128 for K241872, 4 for K242610, 33–34 for the August 2025 clearances, and 6 for K252926; to first archived observation they were 929, 160, 36, 88–89, and 22 days (Fig. 2b). The March 2025 version was not yet displayed in a capture taken one day after its stated date. The table listed K210478 for the S and Si although the clearance indicates the Si only. By contrast, the OEM's annual report for fiscal year 2022 acknowledged a remanufactured S/Si clearance 133 days after the first decision [34].

Postmarket identity

The MAUDE union contained 26 reports received between 11 May and 23 September 2026, all concerning robotic scissors described as remanufactured or reprocessed (Fig. 2c). Twenty-three were notifications by a manufacturer that did not make the device, filed under 21 CFR 803.22(b)(2) [35], one of which names the OEM as notifier; three were user-facility reports. Twenty-three used the OEM product code and three used QSM. Twenty-three lacked a model number; of the three with one, a single report (470179) matched a cohort model. A model-number search for 470179 returned 12,848 records that could not be separated into OEM and remanufactured devices. Narratives described dull or non-cutting blades, sticking jaws, and broken tips. One OEM notification described thermal damage consistent with arcing, a failed dielectric test, and an RFID counter showing three remaining remanufacturer-added uses, the only public field observation of counter state we found; it is an unverified bench observation by a competitor. Patient-outcome fields, where coded, indicated no clinical consequence.

Litigation as a source of device evidence

The event register comprised 49 events (30 court, 9 FDA communication, 5 OEM policy-page, and 5 securities-filing events) and 33 device-event links: 21 exact (15 by name, 6 by unique inference), 10 family-level, and 2 platform-level (Fig. 3; Online Resource 3). Only two of nine models, K210478 and the K242610 scissors, were identified exactly in a court record or filing, and most challenged conduct predated the relevant clearances. No reviewed order adjudicated antitrust liability for conduct involving a cleared remanufacturing process. In the independent servicer case, the Ninth Circuit's August 2026 reversal of the judgment for the OEM stands after the full court denied rehearing en banc on 22 October 2026, returning the case to the district court [29]. In the hospital purchaser class action, the OEM reported a written agreement to settle for $450 million and mutually agreed injunctive relief, without admission of liability and subject to preliminary and final court approval [30, 36, 37]. All nine FDA communications identified about remanufactured or use-extended instruments entered the public record through litigation filings or judicial accounts; none was located as an agency publication.

Coding agreement and adjudication

The two passes agreed on all 90 disclosure codes (κ = 1.00) and on 88 of 90 methods-level codes (quadratic weighted κ = 0.97); both differences concerned the K252926 mechanical-function cells, which adjudication resolved as “named” because the summary lists functional performance testing without a procedure. The passes agreed on the top-level category of all 33 links (κ = 1.00), but the second pass did not reproduce the distinction between named and inferred exact links, so the documented inference basis was retained. Event-status agreement was 33 of 47 (70.2%; κ = 0.64); of the 14 differences, 11 were resolved in favor of the second pass (chiefly FDA communications recounted in court records and complaints) and 3 in favor of the first. No reported count changed after adjudication.

Discussion

This audit identifies a gap between regulatory clearance and point-of-use verification for remanufactured robotic instruments, and shows that the gap is widest where the clinical stakes are highest. Every numeric life extension in the cohort applies to a monopolar energy instrument, the instrument class most often exchanged prematurely and most often linked to device-related injury, yet the public record contains no tested sample size, cycle count, or electrical acceptance limit for any of them. The contribution is a linked, model-level account of four verification links: what was tested, whose testing it was, when clinicians were told, and whether a failure can be traced. It does not show that any cleared instrument is unsafe or that confidential submissions lack data.

Clinical relevance for the robotic surgeon

Insulation breakdown in robotic monopolar instruments is a recognized cause of arcing, stray-energy burns, and vascular injury [5–7], and robot-mounted monopolar instruments retained a burn signal in a recent analysis of FDA surveillance data [38]. A remanufactured scissor in its eleventh or twentieth use is therefore the instrument for which tested electrical integrity matters most, and the public record does not show whether that point in its life was tested. This is a documentation gap, not a failure signal. Until model-level data are available, teams adopting remanufactured energy instruments can apply the vigilance used for any instrument late in its life: pre-use inspection of insulation and tip covers, a low threshold for exchange when cutting performance or insulation integrity is in doubt, and failure reports that name the remanufacturer and model.

Inherited evidence

Predicate-ancestry studies show that claims move through 510(k) networks [11, 12]. Here, public summaries also disclose inherited test methods: four Rebotix summaries cite K241872, K242610 cites K210478, and K252926 cites the OEM’s K203632. Method reuse may be appropriate for near-identical devices, but a count of clearances overstates the number of independent public testing narratives, and a weakness in a root narrative would propagate through its lineage. K252926’s reliance on an OEM reprocessing clearance to support additional uses does not, on the public record, show how test exposure extends beyond the OEM’s labeled life.

Blurred identity in surveillance

Remanufactured instruments keep OEM model numbers, most reports used the OEM product code, and most lacked a model number, so these fields cannot reliably separate OEM from remanufactured devices; misattribution could run in either direction. Forwarding complaints about another firm's device is a permitted route [35], and the OEM may receive returned instruments, but when 23 of 26 reports come from one competitor, report counts reflect reporting pathways as well as device events, and bulk-reporting episodes have been documented in robotic MAUDE data [38]. Only three reports came from user facilities, the reporters with direct clinical knowledge.

Who tells the surgeon

Hospitals often learn about instrument limits from the platform manufacturer, which in this market is also the remanufacturers' competitor and litigation opponent. Its policy page first named a cleared model 897 days after the first clearance, dated one version earlier than it first appeared, and listed one clearance for a platform outside its indication. FDA's own views on use-count extension reached the public only through litigation. Neither channel gives surgeons a neutral, model-specific reference.

Implications

Remanufacturing may lower cost and waste [8–10], and these findings support transparent verification rather than a judgment for or against its use. Table 3 converts the observed gaps into a ten-item model-level verification record that value-analysis and sterile-processing teams can request from a remanufacturer: original labeled life; added uses; counter-reset method; number of instruments and cycles tested; acceptance criteria and results; dielectric and insulation limits for energy instruments; cleaning-residue endpoints [39]; validated sterilization parameters; methods inherited from other clearances; and a device identifier that distinguishes the remanufactured instrument. For regulators, the same items define a minimum public summary for remanufactured instruments, and a remanufacturer-specific identifier visible in adverse-event reports would build on the existing unique device identification framework [40].

Limitations

Public 510(k) summaries are abstracts of confidential submissions, so the findings concern public verifiability rather than FDA's complete review or device performance. Archive captures bound policy-page changes but cannot date them precisely, and two 2025 captures returned an access-denial page. The second coding pass used excerpts selected by the first, so the two passes were not fully independent. MAUDE searches could miss reports that never name remanufacturing, reports are unverified and lack a denominator, and the four-month clustering may reflect reporting behavior. The OEM labeled life used for context comes from published and judicial sources rather than the summaries. Litigation status was checked on 23 October 2026 and may change. The analysis covers one platform in the United States.

Conclusion

For FDA-cleared remanufactured da Vinci instruments, public records let a surgeon confirm the model and its clearance, but not its intended lifetime, the testing behind its added uses, the independence of that testing, or whether an adverse-event report concerns it. The gap is greatest for monopolar energy instruments, which carry every numeric life-extension claim. A ten-item model-level verification record and a remanufacturer-specific device identifier would let surgical teams evaluate these instruments on evidence.

Declarations

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Author contributions: All authors contributed to the study conception and design and to interpretation of the findings. Data collection was performed by Logan Glosser. Data analysis was performed by Snehal Patel. The first draft of the manuscript was written by Logan Glosser, and Snehal Patel critically revised it. Quynh Tran Pac, Tucker Bettis, and Felipe Maegawa critically reviewed and commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Ethics approval: This study analyzed only publicly available regulatory, corporate, court, and adverse-event records and involved no human participants and no identifiable private information. Institutional review board review was therefore not required.

Consent to participate and consent to publish: Not applicable.

Data availability: The coded dataset, codebook, adjudication log, archive-capture log, and analysis code are openly available in Zenodo at https://doi.org/10.5281/zenodo.23605744 and as Online Resources 2 and 3. Source FDA, court, and SEC documents are public and identified in the reference list.

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Tables

Table 1 FDA-cleared remanufactured da Vinci instruments (product code QSM) through 22 October 2026, with predicate, methods reference, and public use-life statement

K number and model	Applicant; decision	Platform	Primary predicate[b]	Methods reference (lineage)	Use-life statement in the public summary
K210478 420179 monopolar curved scissors	Iconocare Health; 30 Sep 2022	Si	K180033	None (root, lineage 1)	Ten additional reuse cycles; original count not stated
K242610 470179 monopolar curved scissors	Iconocare Health; 11 Mar 2025	X, Xi	K220023	K210478 (lineage 1)	Ten cycles, described both as indicated use life and as additional uses[a]
K241872 420093 ProGrasp forceps	Rebotix; 7 Nov 2024	S, Si	K203632	None (root, lineage 2)	Counter reset “to permit an additional controlled set of uses”; number and reset method not stated
K250387 420048 long tip forceps	Rebotix; 19 Aug 2025	S, Si	K203632	K241872 (lineage 2)	As K241872
K250399 420049 Cadiere forceps	Rebotix; 19 Aug 2025	S, Si	K203632	K241872 (lineage 2)	As K241872
K250417 420190 Cobra grasper	Rebotix; 20 Aug 2025	S, Si	K203632	K241872 (lineage 2)	As K241872
K250539 420207 tenaculum forceps	Rebotix; 19 Aug 2025	S, Si	K203632	K241872 (lineage 2)	As K241872
K252926 470183 permanent cautery hook; 470184 permanent cautery spatula	Restore Robotics; 26 Mar 2026	X, Xi	K131861	K203632, an OEM clearance (lineage 3)	Up to ten additional uses beyond the OEM-cleared use life; OEM count not stated

Model numbers are identical to the corresponding OEM catalogue numbers. FDA establishment registration listed K210478, K242610, and K252926 under Restore Robotics Repairs LLC on 23 October 2026; Restore’s pleadings describe Iconocare as its subsidiary (a party allegation). Sources [16–23]

[a] K242610 states that the instrument “is indicated for 10 cycles of use” and that the process “will increase the cycles to 10,” and elsewhere refers to “an additional ten (10) reuse cycles”

[b] All primary predicates are da Vinci instruments or systems cleared under the OEM product code NAY. OEM, original equipment manufacturer

Table 2 Public disclosure by validation domain across eight clearances, and what a hospital cannot verify from the summary

Domain	Specific mention	Generic phrase only	Methods named	Methods described	Not verifiable from any public summary
Mechanical function	8	0	8	0	Number of instruments tested; acceptance limits; results
Durability and life extension	8	0	5	0	Cycles tested; original plus added use count
Electrical and thermal	8	0	8	0	Insulation and dielectric limits and results
Cleaning and residues	2	6	2	2	Residue limits and results
Sterilization	0	8	0	0	Validated sterilization parameters
Biocompatibility	8	0	8	0	Endpoints tested and results
Software and cybersecurity	5	0	5	0	Counter-reset method; change control (3 clearances: applicability unclear)
Packaging and storage	0	0	0	0	Packaging and storage conditions (8: applicability unclear)
Traceability and labeling	0	0	0	0	How the remanufactured instrument is marked and traced
Clinical outcomes	0	0	0	0	Any clinical performance data

Counts are clearances (n = 8); K252926 covers two models with one narrative. Across 90 model-domain cells: specific mention 44, generic phrase only 15, no mention 31; methods named 40, described 3; consensus standard or FDA guidance cited 19. No cell reported a test sample size, test-cycle exposure, acceptance criterion, or numeric result. Absence from a public summary does not indicate absence from the confidential submission. Model-level coding is in Fig. 1 and Online Resource 2

Table 3 Ten-item model-level verification record: what the public 510(k) summaries disclose for each cleared model

Verification item	K210478 scissors (Si)	K242610 scissors (X/Xi)	K241872 forceps (S/Si)	K250387, K250399, K250417, K250539 graspers (S/Si)	K252926 hook and spatula (X/Xi)
1. Original OEM-labeled use count	No	Unclear[a]	No	No	No
2. Number of added uses	10	10[a]	Not stated[b]	Not stated[b]	10
3. Counter-reset method	No	No	No[b]	No[b]	No
4. Instruments and cycles tested	No	No	No	No	No
5. Acceptance criteria and results	No	No	No	No	No
6. Dielectric or insulation limits (energy instruments)	No	No	n/a	n/a	No
7. Cleaning-residue endpoints	No	Analytes named; no limits	No	No	Analytes named; no limits
8. Validated sterilization parameters	No	No	No	No	No
9. Source of test methods	Own (lineage root)	K210478	Own (lineage root)	K241872	K203632 (OEM clearance)
10. Identifier distinct from the OEM model number	No	No	No	No	No

Derived from the coded summaries (Online Resource 2). Every clearance identifies its model, platform, and regulatory status. Items 1–8 and 10 are the information a hospital would need to request directly from the remanufacturer. OEM, original equipment manufacturer

[a] K242610 describes ten cycles both as the indicated use life and as additional uses (see Table 1, footnote a)

[b] Counter reset “to permit an additional controlled set of uses”; neither the number of uses nor the reset method is stated

Figures

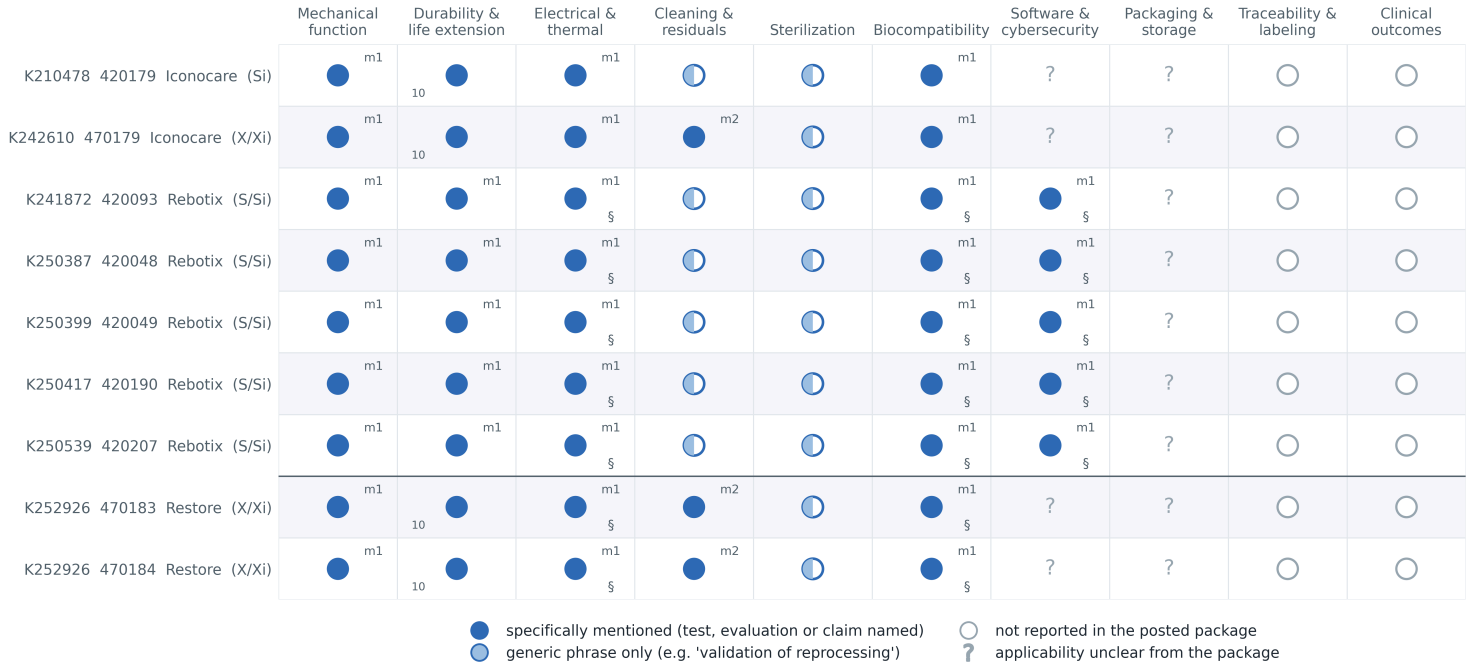


Figure 1

Model-by-domain public disclosure for nine models under eight QSM clearances. Filled circle, specific mention; half-filled, generic phrase only; open, no mention; question mark, applicability unclear from the summary. m1, test type or standard named; m2, procedure or analyte described; §, consensus standard or FDA guidance cited; 10, labeled ten-additional-use claim (not a test exposure). The two K252926 rows share one narrative

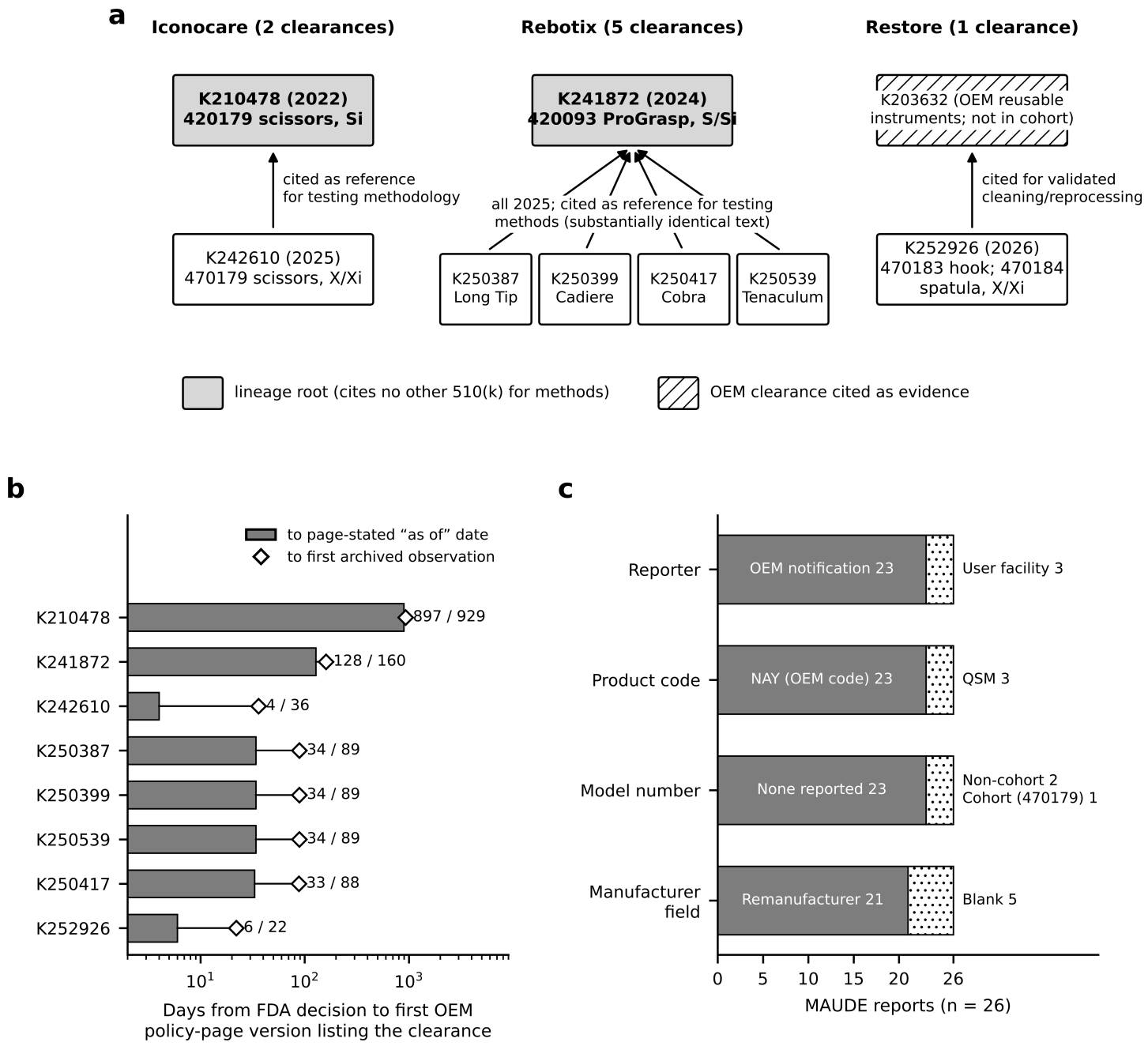


Figure 2

Three public-record gaps. **a** Evidence lineages: clearances connected by explicit citation of another 510(k) as the reference for test or reprocessing methods; gray, lineage root; hatched, OEM clearance cited as evidence. **b** Days from FDA decision to the first OEM policy-page version listing each clearance (log scale): bars, to the page's stated "as of" date; diamonds, to the first Internet Archive capture showing that version. **c** Identity fields in 26 MAUDE reports on remanufactured or reprocessed scissors. MAUDE, Manufacturer and User Facility Device Experience; OEM, original equipment manufacturer

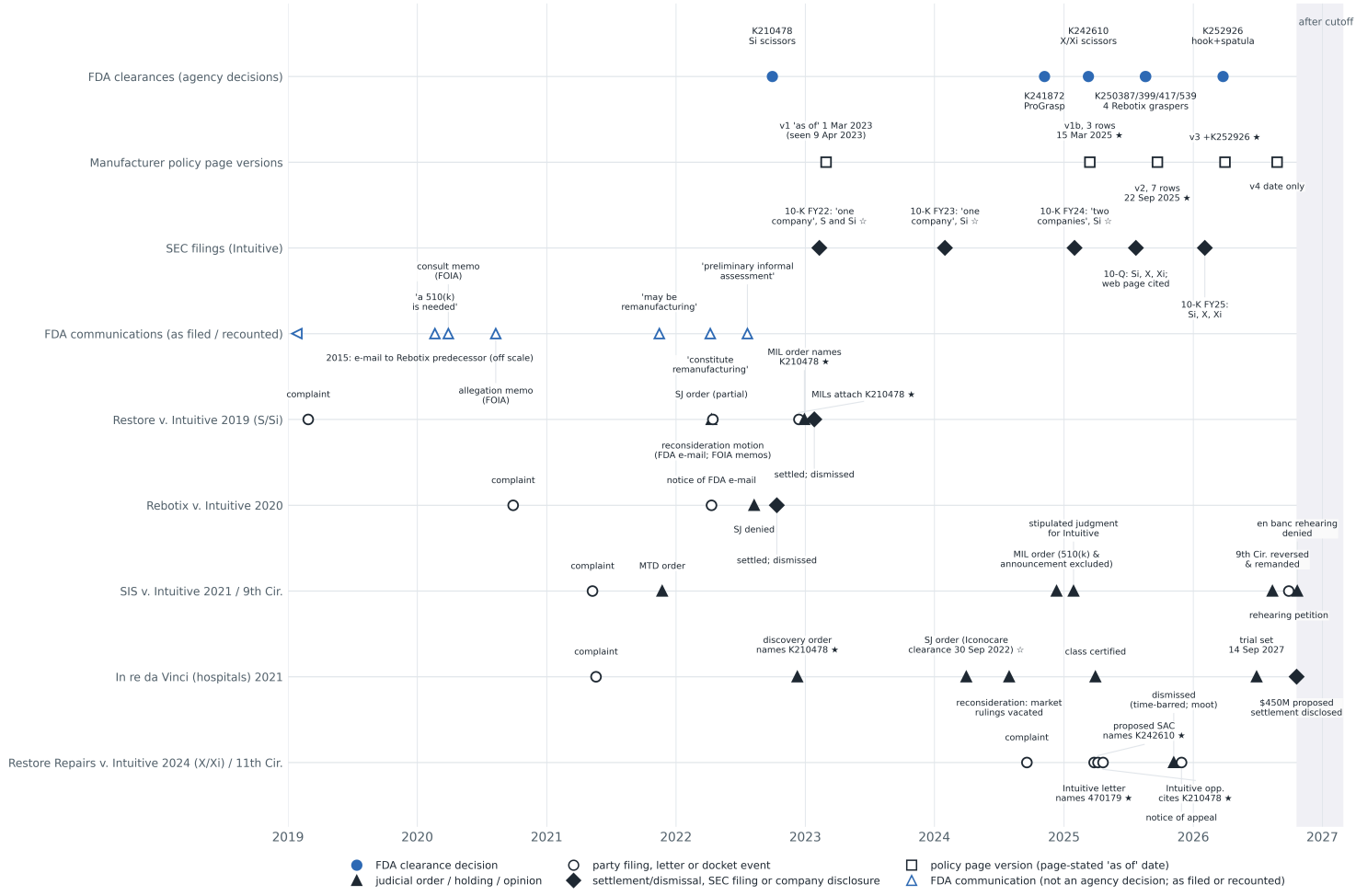


Figure 3

Chronology, 2019–2026, of FDA clearances, OEM policy-page versions, OEM securities filings, FDA communications (as filed by parties or recounted by courts; none an agency decision), and five litigation families. Filled star, the source names a cohort K number or model; open star, the clearance is identified by unique inference. Policy versions are plotted at the page's stated "as of" date. Sequence does not imply causation, and no event is a liability finding. OEM, original equipment manufacturer

Supplementary Files

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

- ESM1.pdf
- ESM2.xlsx
- ESM3.xlsx