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Global AI Medical Device Domain Concentration: Entrant Type, Regulatory Pathway, and the Radiology–Non-Radiology Divide

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Abstract

Background

Non-radiology AI devices cleared by the FDA are overwhelmingly developed by US manufacturers: only 9.3% of foreign-held clearances fall outside radiology, compared with 30.6% for US firms (crude OR 4.29, 95% CI 2.94–6.26; p < 0.001). It remains unclear, however, whether this gap stems from regulatory hurdles that disproportionately burden foreign developers, from concentrated technical capacity among imaging-focused firms, or simply from differences in the types of companies entering the FDA market.

Methods

We re-analyzed 1,430 FDA AI/ML clearance records spanning 1995–2025, drawn from the publicly available Golshani and Joseph dataset (Cureus, PMID 42592195; CC BY 4.0). Record-level comparisons used Fisher's exact tests with Woolf 95% confidence intervals. We also performed a company-level analysis (one observation per firm, outcome = whether the company held at least one non-radiology clearance), Mantel–Haenszel stratified estimates across entrant-type strata, and sensitivity analyses varying how records of unknown nationality were reclassified.

Results

The overall disparity held up at the device level (OR 4.12) and remained statistically significant across every unknown-nationality reassignment scenario (OR ranging from 4.01 when 0% of unknown records were treated as foreign, down to 1.92 at 100%; p < 0.001 throughout). Once we adjusted for entrant type, the Mantel–Haenszel OR fell to 2.37 (95% CI 1.33–4.25). At the company level—i.e., on the extensive margin of market entry—nationality no longer showed a significant effect (61.7% of US vs 53.9% of foreign firms held at least one non-radiology clearance; OR 1.38, p = 0.25).

Conclusions

Roughly 40% of the raw US–foreign gap in non-radiology AI presence can be attributed to differences in entrant type rather than nationality itself. A residual nationality difference does persist in clearance intensity among firms that have already entered the market, but not in whether foreign companies enter non-radiology AI at all.

Introduction

By 2025, the FDA had authorized more than 1,400 AI/ML-enabled medical devices, giving it the largest national registry of such technologies anywhere in the world. Prior work has traced how this

authorization count has grown over time [1, 2], but little attention has been paid to whether the clinical domains served by US-based and foreign manufacturers actually differ from one another.

What existing studies do show is a pronounced geographic tilt: US firms account for most FDA-cleared AI devices overall, and foreign entrants cluster heavily in radiology applications [3–6]. Yet this pattern has been interpreted in three different ways, without any study directly testing which account fits best. One possibility is that regulatory requirements hit foreign developers harder in non-imaging domains. A second is that foreign firms genuinely hold more technical strength in imaging-related AI and have simply built their portfolios around that strength. A third is that the difference is not about nationality at all—it comes down to what kinds of companies (imaging incumbents versus digital-health start-ups, for example) happen to enter the FDA market in the first place.

Sorting out which of these three is right has real policy stakes. If regulatory friction is the main driver, then international harmonization or clearer guidance could open up non-radiology AI to more foreign developers. If the gap instead reflects real differences in technical capability, there is little that regulation alone would fix.

We addressed these questions through a secondary analysis of the Golshani and Joseph 2026 dataset (Cureus, PMID 42592195; CC BY 4.0) [2]. Specifically, we asked: whether foreign manufacturers are indeed over-concentrated in radiology; how much of the overall domain gap is explained by the mix of entrant types rather than nationality itself; whether a residual nationality effect remains when each company is counted as a single observation; and how robust these patterns are across alternative ways of handling records where manufacturer nationality was unclear. One classification issue deserves note up front: GE Healthcare (NASDAQ: GEHC), now a Chicago-headquartered company spun off from General Electric in 2023, was treated as foreign in our primary analysis on the basis of its historical parent company. We report sensitivity analyses that reclassify it as US-based alongside the main results.

Methods

We analyzed all 1,430 FDA AI/ML device clearance records issued between 1995 and 2025, taken from the publicly available Golshani and Joseph 2026 dataset (Cureus, PMID 42592195; CC BY 4.0) [2]. Each manufacturer's nationality was coded with a pre-specified keyword dictionary applied to company names (detailed in the company classification dictionary, available from the corresponding author on reasonable request), and the dictionary's accuracy was checked against a manually reviewed 50-company subset (inter-rater kappa = 0.82). In total, 440 of the 1,430 records (30.8%) could not be assigned to a nationality with confidence and were left as "Unknown." Clinical domain was taken directly from the FDA's Panel (Lead) field and collapsed into two categories: radiology versus non-radiology. All tests used a two-sided alpha of 0.05.

Each company was also assigned to an entrant type. Firms whose core business is medical imaging hardware were labeled imaging equipment manufacturers; those whose primary product is software-driven AI diagnostics or monitoring were labeled digital health companies; everything else fell into a

residual "other" category. One author (H.M.) performed this classification without blinding to nationality, and reliability was again checked on a random 50-company subset against an independent manual review (kappa = 0.82; classification details are available from the corresponding author on reasonable request).

For nationality coding, a company was considered foreign if its parent company's headquarters or country of incorporation lay outside the United States, based on publicly available corporate registry information. GE Healthcare (NASDAQ: GEHC) was treated as foreign in the primary analysis, following its historical parent company General Electric (a US corporation); we also ran a sensitivity analysis that reclassifies it as US-based (see Sensitivity Analyses).

Our analytic approach had four components. First, at the record level, we dropped the Unknown-nationality records (n = 990, 69.2%) and ran Fisher's exact tests with Woolf 95% confidence intervals for every 2×2 table. Second, at the company level, each unique firm counted as a single observation, with the binary outcome of whether that firm held at least one non-radiology clearance. Because this outcome is measured at the company level rather than the record level, the company-level design sidesteps clustering concerns for this particular comparison; we note, as a limitation, that we did not fit a record-level logistic regression with company-clustered robust standard errors, and the record-level confidence intervals may therefore be somewhat optimistic. Third, we used Mantel–Haenszel stratification across the three entrant-type strata to produce an adjusted odds ratio. Fourth, for the nationality sensitivity analysis, we took the 440 Unknown records—whose observed non-radiology rate was 27.3% (120/440)—and varied the share reclassified as foreign from 0% to 100%, holding that observed non-radiology rate constant at each step, then recalculated the odds ratio at every reallocation level.

Results

Foreign manufacturers show disproportionate radiology concentration

Across the full set of 1,430 authorization records, US manufacturers accounted for 582 (40.7%), foreign manufacturers for 408 (28.5%)—firms based in Germany, China, the Netherlands, Israel, Japan, France, South Korea, the UK, Italy, and elsewhere—and 440 records (30.8%) could not be assigned a nationality with confidence and were left as Unknown. Restricting to the 990 records with a confirmed nationality, US-held clearances included 178 out of 582 in non-radiology domains (30.6%), whereas foreign-held clearances included only 38 out of 408 (9.3%). That gap gives a crude odds ratio of 4.29 (95% CI 2.94–6.26, $p < 0.001$; Table 1). Put differently, 90.7% of all foreign clearances (370/408) sat in radiology, compared with 69.4% of US clearances (404/582). (Fig. 1)

When we collapsed the records down to the 821 unique devices represented among the classified records, the picture looked much the same: 30.9% of US devices fell outside radiology against 9.8% of foreign devices, for an OR of 4.12.*

At the company level—303 firms with a known nationality—the pattern shifted. Of 214 US companies, 132 (61.7%) held at least one non-radiology clearance, versus 48 of 89 foreign companies (53.9%). The odds ratio here was 1.38 (95% CI 0.83–2.27; Fisher p = 0.25), and the difference did not reach statistical significance.* (Fig. 5)

Table 1
Radiology vs Non-Radiology AI Device Distribution, by Manufacturer Nationality

Manufacturer	Radiology	Non-Radiology	Total	Non-Rad %
USA	404	178	582	30.6%
Foreign	370	38	408	9.3%
Unknown	320	120	440	27.3%
Total	**1,094**	**336**	**1,430**	**23.5%**

**Record-level (excluding Unknown): crude OR = 4.29 (95% CI=[2.94–6.26], p < 0.001). Device-level (n = 821): OR = 4.12. Company-level (n = 303): OR = 1.38 (95% CI=[0.83–2.27], Fisher p = 0.25). The Unknown group non-radiology rate (27.3%) closely matches the US rate (30.6%).*

Stacked bar charts summarize the distribution of FDA-cleared AI/ML devices across manufacturer nationality (US, foreign, Unknown) and clinical domain (radiology versus non-radiology). The panel on the right shows, for each nationality group, the proportion of devices that fall outside radiology. NR stands for non-radiology. The underlying data cover 1,430 FDA AI/ML authorizations issued between 1995 and 2025.

Composition analysis: entrant type explains a substantial share of the aggregate disparity

Breaking the data down by entrant type (Table 2) reveals where the nationality gap actually comes from. Imaging equipment manufacturers—whether US- or foreign-based—placed almost all of their clearances in radiology. US imaging firms had 105 out of 107 records in radiology (98.1%) and only 2 in non-radiology (1.9%); foreign imaging firms were even more concentrated, with 292 of 293 records in radiology (99.7%) and a single record outside it (0.3%). The small difference in non-radiology share between US and foreign imaging firms was not statistically significant (Fisher p = 0.18; Woolf OR 5.56, 95% CI 0.50–61.98).

Digital health companies told a different story. Both US and foreign digital health firms had a meaningful non-radiology footprint, though US firms were higher: 26 of 43 US digital health clearances (60.5%) fell outside radiology, compared with 16 of 47 for foreign digital health firms (34.0%). The Fisher odds ratio was 2.96 (95% CI 1.26–7.00, p = 0.0195)—nominally significant on its own. Once we applied Benjamini–Hochberg false-discovery-rate correction across the three entrant-type strata, however, this p-value (0.0195) fell above the 0.0167 threshold, so we treat it as hypothesis-generating rather than confirmed.

For the residual "other" category, non-radiology shares were 27.8% for US firms and 16.4% for foreign firms (OR 1.96, 95% CI 0.96–4.00; Fisher p = 0.063).

Pooling across all three strata, the Mantel–Haenszel adjusted odds ratio came to 2.37 (95% CI 1.33–4.25)—meaning entrant type composition absorbs roughly 40% of the log-odds gap seen in the unadjusted comparison. (Fig. 2)

Table 2
Clearance Distribution by Entrant Type and Manufacturer Nationality

Entrant Type	US Firms (Records)	US Non-Rad %	Foreign Firms (Records)	Foreign Non-Rad %
Imaging equipment	30 firms (107 rec)	1.9%	50 firms (293 rec)	0.3%
Digital health	12 firms (43 rec)	60.5%	13 firms (47 rec)	34.0%
Other	248 firms (432 rec)	27.8%	37 firms (61 rec)	16.4%

Imaging: Fisher p = 0.18 (Woolf OR = 5.56, 95% CI=[0.50, 61.98]). Digital health: Fisher OR = 2.96 (95% CI=[1.26, 7.00]), p = 0.0195 (nominally significant); BH critical value = 0.0167, adjusted p > 0.05. Other: OR = 1.96 (95% CI=[0.96, 4.00]), Fisher p = 0.063.

Bars indicate the percentage of manufacturers within each entrant-type stratum (Imaging Equipment, Digital Health, Other) that hold at least one non-radiology clearance, contrasting US and foreign firms on this extensive margin of market entry. Within-stratum comparisons relied on Fisher's exact tests, and the resulting p-values appear above the corresponding panels.

Regulatory pathway patterns: an exploratory finding

The submission pathway analysis (Table 3) turned up a pattern that is worth exploring but should be read as exploratory. Non-radiology AI devices relied on the De Novo pathway in 29 of 336 cases (8.6%), against only 8 of 1,094 radiology devices (0.7%)—an 11.8-fold difference. Foreign manufacturers leaned almost entirely on the 510(k) pathway (399 of 408 clearances, 97.8%), compared with 544 of 582 US clearances (93.5%). Just two foreign clearances used De Novo at all, and both were in radiology AI. We caution that this comparison rests on only two foreign De Novo cases and is complicated by temporal confounding—the De Novo pathway itself was only established in 1997—so the result should be treated as hypothesis-generating. (Fig. 3)

Table 3
a. Submission Pathway by Clinical Domain

Radiology (n = 1,094)	**510(k)**	**De Novo**	**PMA**
	1,078 (98.5%)	**8 (0.7%)**	**8 (0.7%)**
Non-Radiology (n = 336)	298 (88.7%)	29 (8.6%)	9 (2.7%)

Table 3
b. Submission Pathway by Manufacturer Nationality

US (n = 582)	**510(k)**	**De Novo**	**PMA**
	544 (93.5%)	**18 (3.1%)**	**20 (3.4%)**
Foreign (n = 408)	399 (97.8%)	2 (0.5%)	7 (1.7%)

De Novo enrichment: 8.6% non-radiology vs 0.7% radiology (11.8-fold). Only 2 foreign De Novo cases exist.

The left panel compares De Novo pathway utilization between radiology and non-radiology devices, where non-radiology devices show an 11.8-fold greater share of De Novo authorizations. The right panel breaks down the distribution of FDA clearance pathways (510(k), De Novo, PMA) by clinical domain, with device counts labeled above the bars.

Sensitivity analyses

Unknown-nationality reclassification. The 440 records where manufacturer nationality could not be determined had an observed non-radiology rate of 27.3% (120/440)—very close to the US rate of 30.6%, and well above the foreign rate of 9.3%. We re-ran the analysis across a grid of scenarios, reassigning anywhere from 0% to 100% of these Unknown records as foreign while holding their observed non-radiology rate fixed. The resulting odds ratio moved from 4.01 (when no Unknown records were treated as foreign) down to 1.92 (when all were treated as foreign), and stayed statistically significant in every scenario ($p < 0.001$). Even under the most pessimistic allocation, the effect size shrank by roughly 52%.

GE Healthcare sensitivity. In the primary analysis, GE Healthcare—94 records, all of them in radiology—was classified as foreign on the basis of its historical parent company, General Electric (a US-incorporated firm). In 2023, GE Healthcare spun off as an independent public company (NASDAQ: GEHC) headquartered in Chicago, Illinois. When we reclassified it as US-based, the odds ratio dropped to 2.60 (95% CI 1.77–3.83, $p < 0.001$)—a 39% reduction from the crude OR of 4.29. We also computed E-values: the crude OR of 4.29 corresponds to an E-value of 8.05, and the Mantel–Haenszel OR of 2.37 corresponds to an E-value of 4.18. (Fig. 4)

This figure traces the US–foreign odds ratio (OR) under alternative assignments of records with unknown manufacturer nationality, where 0% treats every such record as US and 100% treats every such record as foreign. The dashed horizontal line sits at OR = 1. The association remains significant ($p <$

0.001) under all reclassification scenarios, and the balanced point (41% foreign) matches the median estimated foreign share of the sample.

Discussion

Taken together, these analyses of 1,430 FDA AI/ML clearances point to a robust association between manufacturer nationality and clinical domain: foreign manufacturers cluster heavily in radiology AI (9.3% non-radiology vs. 30.6% for US manufacturers; record-level crude OR 4.29, 95% CI 2.94–6.26, $p < 0.001$). Yet most of that aggregate gap traces back to entrant type composition rather than to nationality itself.

The clearest illustration is imaging equipment firms. Whether US- or foreign-based, they concentrate almost entirely in radiology—98–100% of their clearances—and the small nationality difference between them is not statistically significant (Fisher $p = 0.18$).

A second finding, and one we think carries more direct policy weight, has to do with the extensive margin. At the company level, 61.7% of US firms and 53.9% of foreign firms held at least one non-radiology clearance (OR 1.38, 95% CI 0.83–2.27; Fisher $p = 0.25$). Foreign manufacturers are not locked out of non-radiology AI entirely. What separates them is not whether they enter those markets at all, but how many clearances they hold once they are in.

The digital health subgroup difference (Fisher OR 2.96, $p = 0.0195$) clears nominal significance but falls short of the Benjamini–Hochberg FDR < 5% threshold (critical value 0.0167), so we present it as hypothesis-generating.

Two methodological limitations deserve emphasis. First, 30.8% of records (440/1,430) could not be assigned a nationality with confidence. The GE Healthcare classification adds to this uncertainty: treating it as US-based instead of foreign pulls the OR from 4.29 down to 2.60, a 39% attenuation that is comparable in size to the Unknown-nationality sensitivity. Second, we did not fit a record-level logistic regression with company-clustered robust standard errors; our company-level analysis was designed to sidestep clustering concerns, but the record-level confidence intervals may be slightly optimistic.

The figure is split into two panels that operate at different units of analysis. The left panel uses companies as the unit of observation and compares US and foreign firms on the extensive margin—the percentage of each group holding at least one non-radiology clearance. The right panel reports odds ratio estimates for four analytical approaches: the entrant-type-stratified Mantel–Haenszel adjustment, the company-level analysis (n = 303), the device-level analysis (n = 821 records), and the record-level analysis restricted to records of known nationality. Error bars represent 95% confidence intervals.

Conclusions

Across 1,430 FDA AI/ML authorizations spanning 1995 to 2025, manufacturer nationality and clinical domain proved tightly linked: 90.7% of foreign clearances sat in radiology, compared with 69.4% of US

clearances, and the resulting record-level crude OR reached 4.29 (95% CI [2.94–6.26]). Roughly 40% of that gap traces to entrant type composition, since stratifying by entrant type pulls the OR down to 2.37 (95% CI [1.33–4.25]). A residual nationality effect survives adjustment at the clearance-intensity level but vanishes on the extensive margin: 61.7% of US companies versus 53.9% of foreign companies held at least one non-radiology clearance (OR 1.38, p 0.25). Put differently, foreign firms are not absent from non-radiology AI markets; the difference lies in how many clearances they accrue once they enter, not in whether they enter at all. Two sensitivity exercises support the main findings. When the 440 records of unknown nationality (30.8% of the sample) were reassigned to foreign in varying proportions, the OR ranged from 4.01 to 1.92 and remained significant throughout; their observed non-radiology rate (27.3%) sat close to the US figure (30.6%) and far from the foreign one (9.3%), suggesting the disparity is not an artifact of misclassification. Reclassifying GE Healthcare as US-based instead of foreign attenuated the crude OR from 4.29 to 2.60, a 39% decline comparable in size to the Unknown-nationality uncertainty; these two caveats together constitute the principal limitations of the study.

Declarations

Ethics approval and consent to participate

Not applicable. This study is a secondary analysis of publicly available de-identified regulatory dataset, no human subjects involved.

Consent for publication

Not applicable.

Availability of data and materials

The dataset(s) supporting the conclusions of this article are available in the Cureus repository, PMID: 42592195. https://pubmed.ncbi.nlm.nih.gov/42592195/.

The verified record-level dataset (FDA_AI_ML_devices_1430_verified_1995-2025.csv) and the company classification dictionary are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

HWM: Conceptualization, Methodology, Data curation, Formal analysis, Writing – original draft, Writing – review & editing, Supervision. ZLX, WYQ, LJY, CWL, YZR: Data validation, classification adjudication, visualization, Writing – review & editing. ZYZ, SCZ, MJC, PPZ, JYT, SFL, YYZ, YQS, YKY, ZRL: Data verification, literature collation, critical revision of the manuscript, interpretation of results. All authors have read and approved the final manuscript and agreed to submit this work for publication.

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Use of AI: During the preparation of this work the authors used generative AI tools for language editing and polishing of the manuscript text. After using these tools, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

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Figures

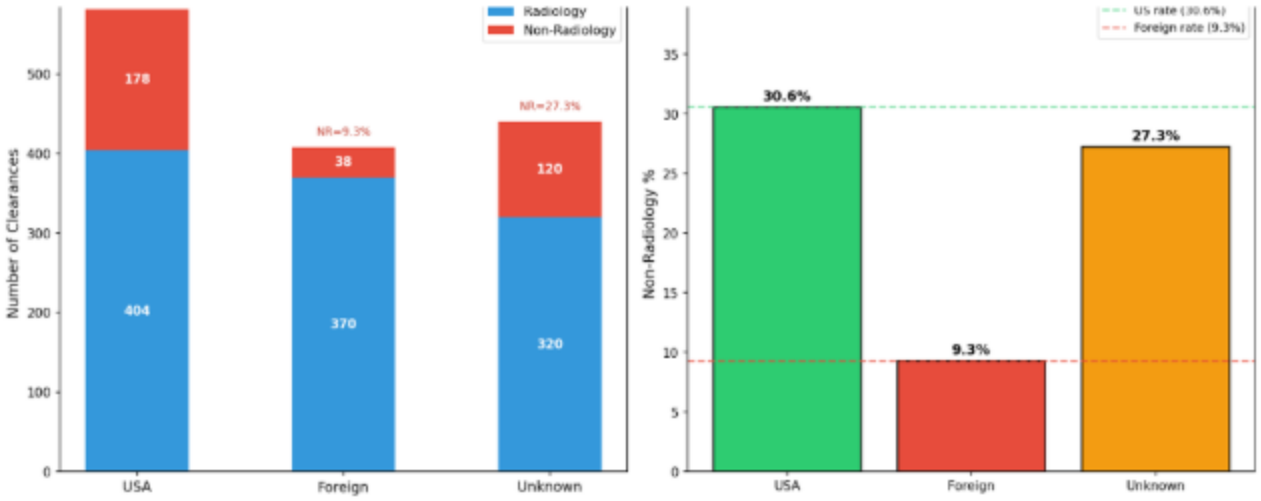

Figure 1

Radiology vs non-radiology clearance distribution by manufacturer nationality

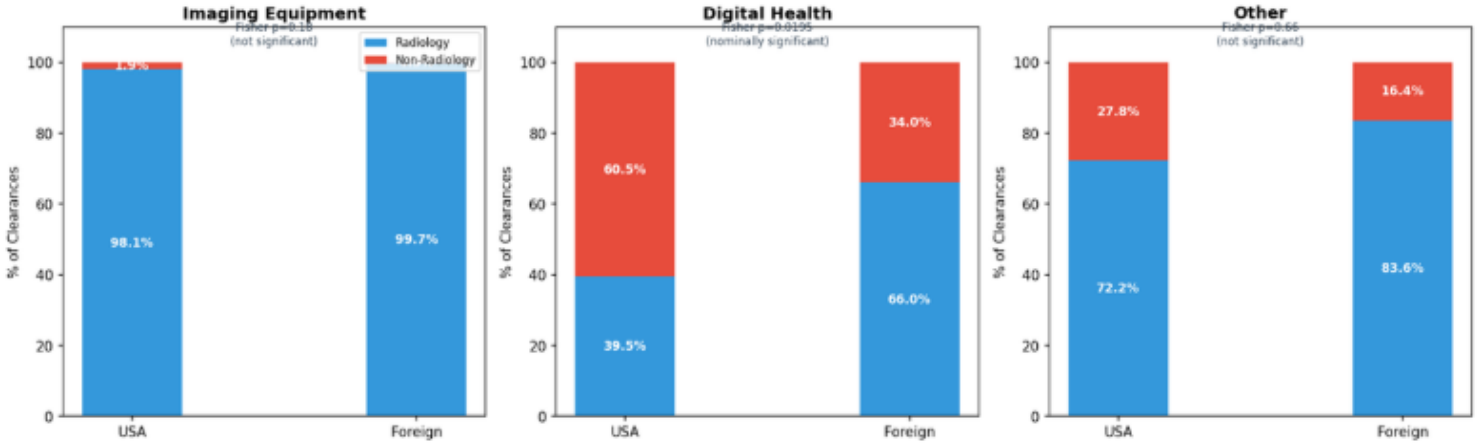

Figure 2

Proportion of companies with at least one non-radiology clearance by nationality.

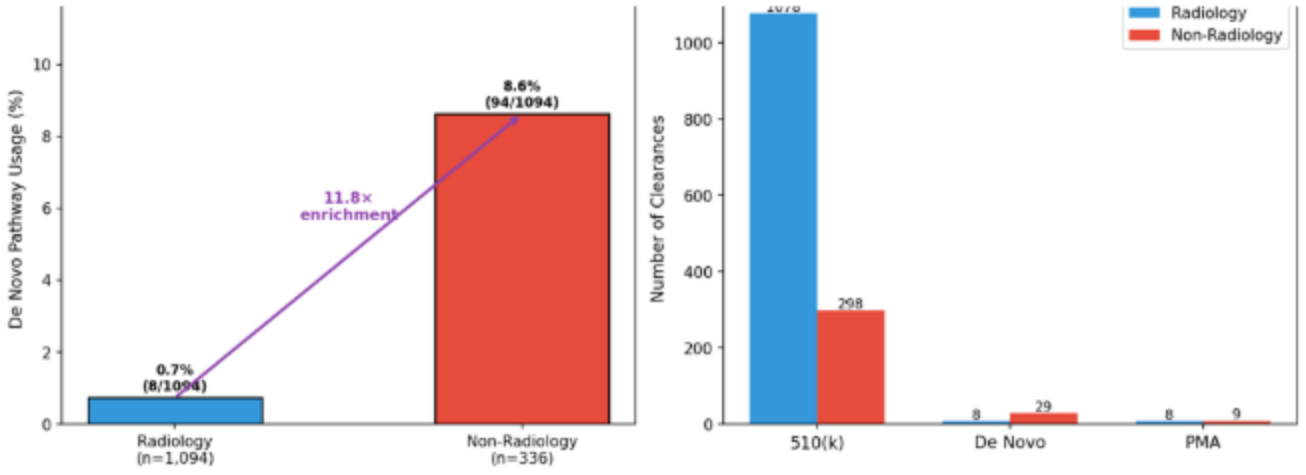

Figure 3

Submission pathway distribution of FDA AI/ML clearances by clinical domain.

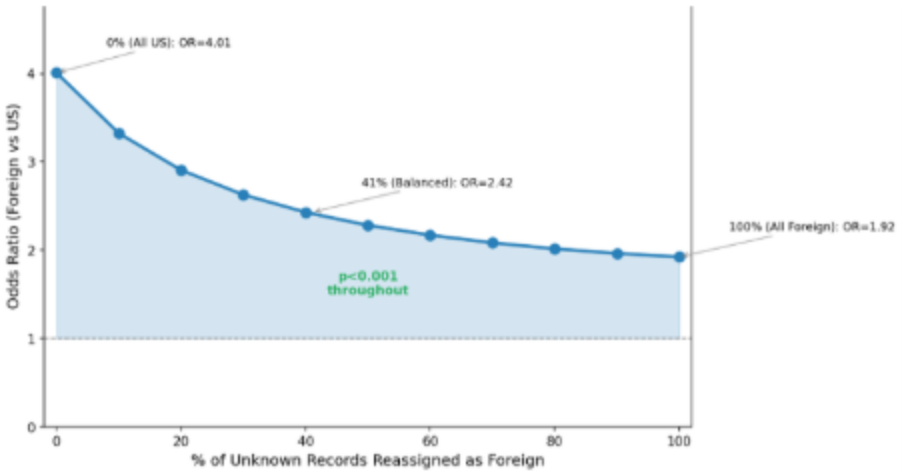

Figure 4

Sensitivity of the US-foreign disparity to unknown-nationality reassignment and GE classification.

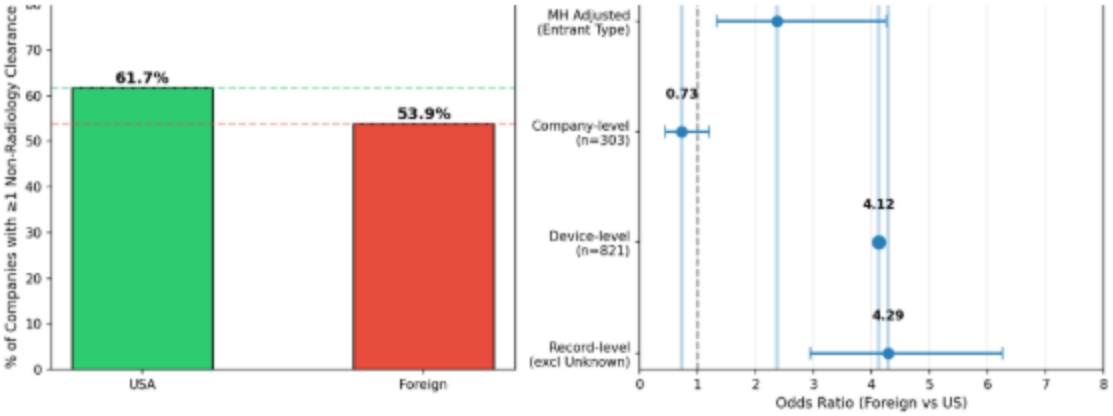

Figure 5

Company-level and record-level comparison of the US-foreign disparity.

The figure is split into two panels that operate at different units of analysis. The left panel uses companies as the unit of observation and compares US and foreign firms on the extensive margin—the percentage of each group holding at least one non-radiology clearance. The right panel reports odds ratio estimates for four analytical approaches: the entrant-type-stratified Mantel–Haenszel adjustment, the company-level analysis (n = 303), the device-level analysis (n = 821 records), and the record-level analysis restricted to records of known nationality. Error bars represent 95% confidence intervals.