# Medical Device Update: 2025 Year in Review

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# Agenda

Premarket Issues

Recalls and Inspections

Warning Letters and Enforcement

Legislation, Rulemaking, and Guidance

Staffing and Shutdowns

# Premarket Issues

Key Developments

Notable Trends

2026 Predictions




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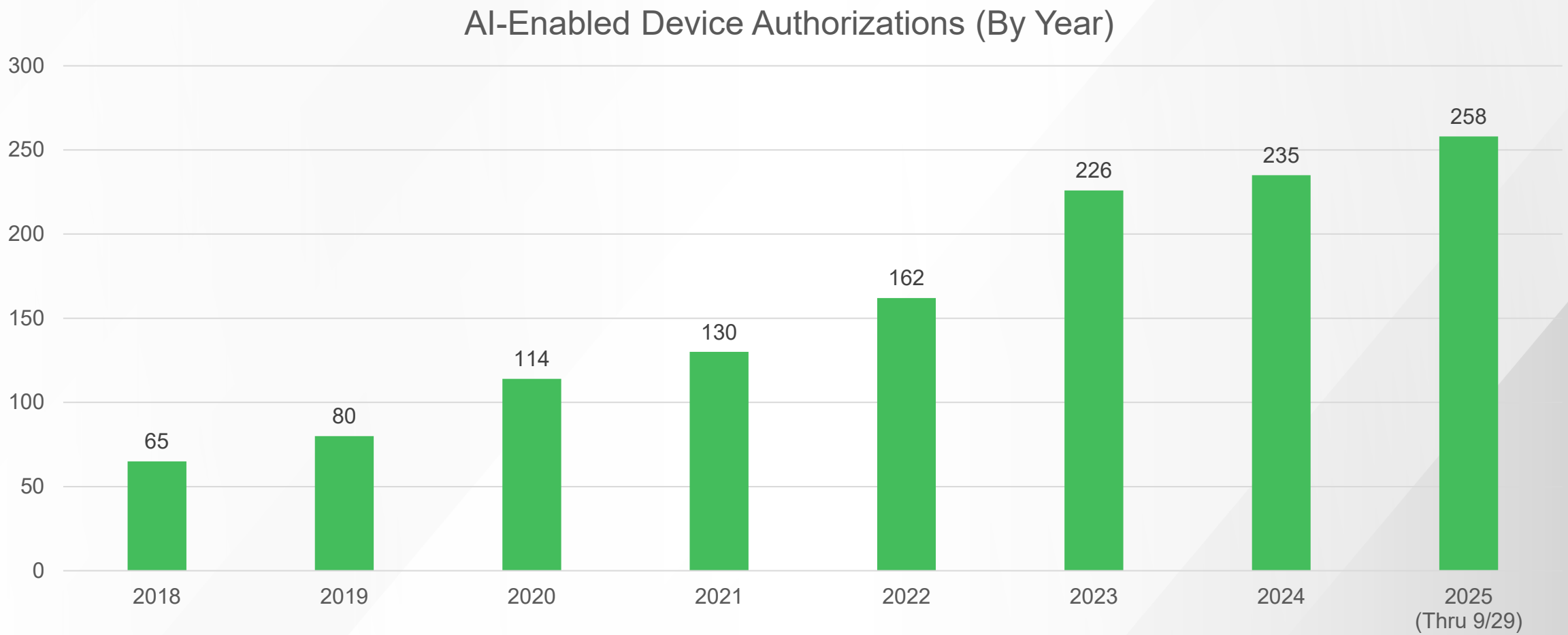
# Premarket Issues: Developments

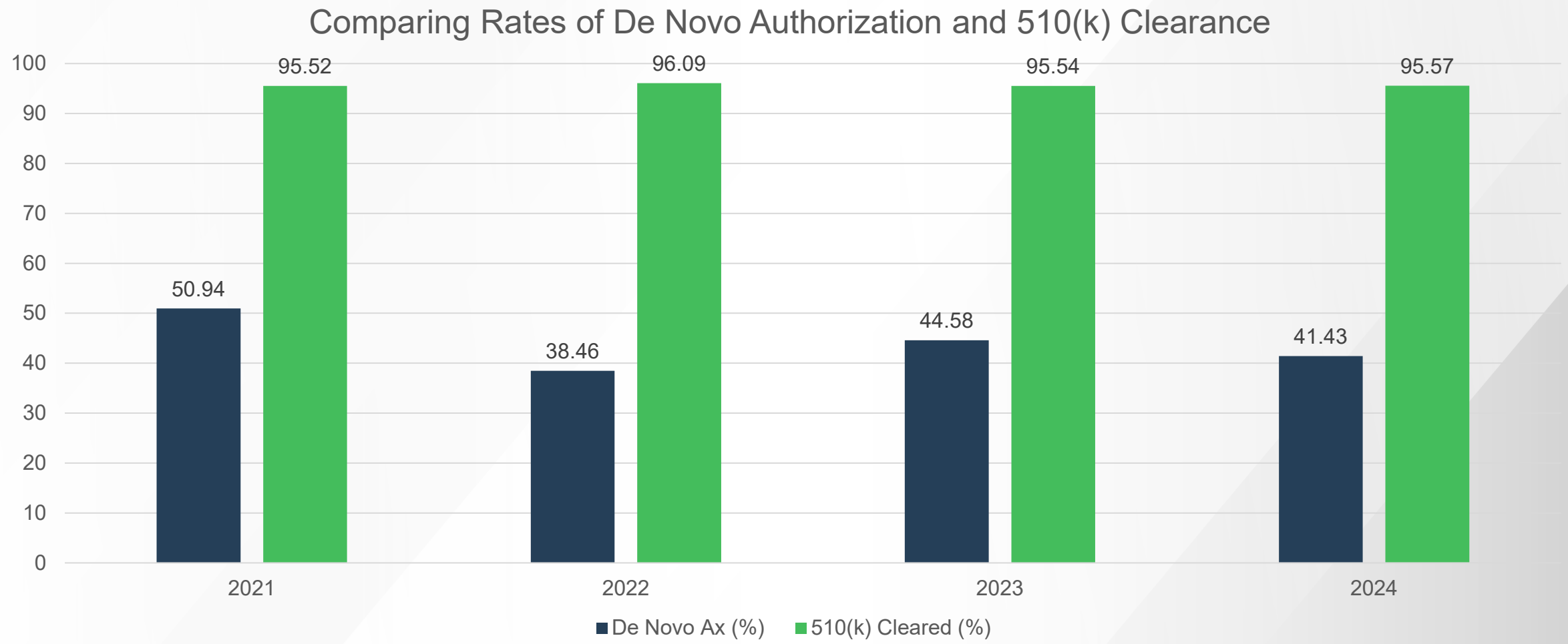
- **Falsified Data from Chinese Testing Laboratories**
  - FDA issued General Correspondence Letters to Mid-Link Technology Testing (Feb. 26, 2025) and Sanitation & Equipment Technology Institute (May 8, 2025) after determining biocompatibility, animal, and performance testing conducted by these companies were falsified or otherwise invalid
  - FDA will reject testing data generated by these entities if used in any premarket device submissions
  - Follows 2024 Warning Letters citing these companies for GLP and data integrity issues
- **Breakthrough Designations**
  - BDD granted to 1,176 devices since 2015
  - Only 160 ultimately received FDA authorization (13.6%)
  - Disconnect between promising early feasibility data and FDA's pivotal study expectations
- **eSTAR Required for De Novo**
  - Mandatory as of Oct. 1, 2025

# Premarket Issues: Trends




**Number of Devices Containing AI is Accelerating**

# Premarket Issues: Trends




**De Novo Pathway Has Lower Chance of Success than 510(k)**

# Premarket Issues: Predictions

- **Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices Pilot**
  - Digital health devices offered to or by participants in the CMMI ACCESS model—a new payment option emphasizing patient outcomes—can request FDA enforcement discretion for premarket review requirements
  - TEMPO participants need to collect real-world data on the intended uses subject to enforcement discretion, share the data with FDA, and use that data to seek marketing authorization from FDA
  - FDA will collect statements of interest for pilot participation beginning in 2026
- **FDA Announces Broader Use of AI for Premarket Review**
  - FDA announced in Dec. 2025 that it will offer FDA staff a broader set of AI tools to use in premarket reviews (and other purposes)
  - Previously, anonymous FDA officials reported the AI hallucinated and cited studies that did not exist

# Recalls and Inspections

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# Recalls: Developments

## Top 5 Root Causes for Recall Events

– Device design
– Process controls
– Software design
– Nonconforming material/component
– Lack of marketing application

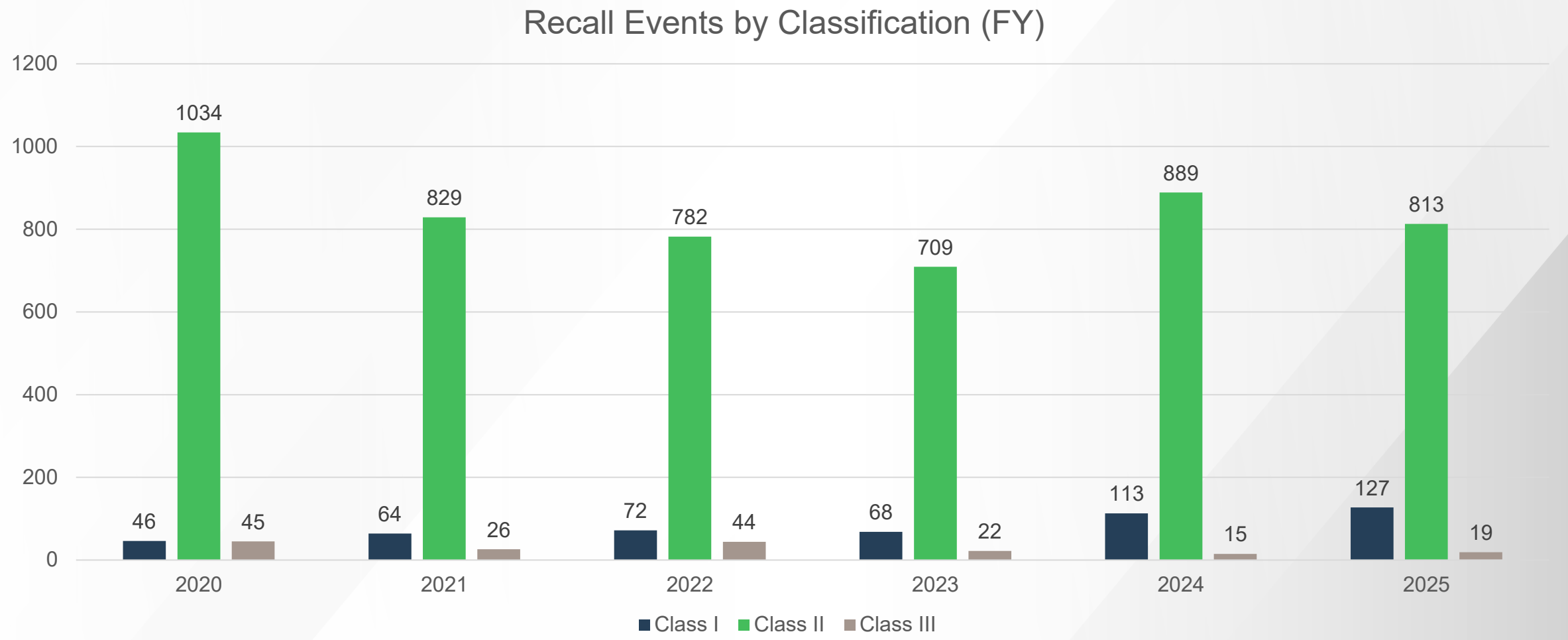
## Early Alert Program

FDA expanded the pilot Early Alert system to include all serious medical device recalls

- Pilot program was initiated in Nov. 2024 – limited to Class I recalls involving cardiovascular, gastrorenal, general hospital, obstetrics and gynecology, and urology devices
- Allows FDA to publicize a potentially high-risk recall within 1-3 weeks of a customer notification
- Database of all recalls subject to the early alert program is available on FDA's website – searchable and updated with new information

**Number and reasons for recalls remained steady in FY2025**

# Recalls: Trends



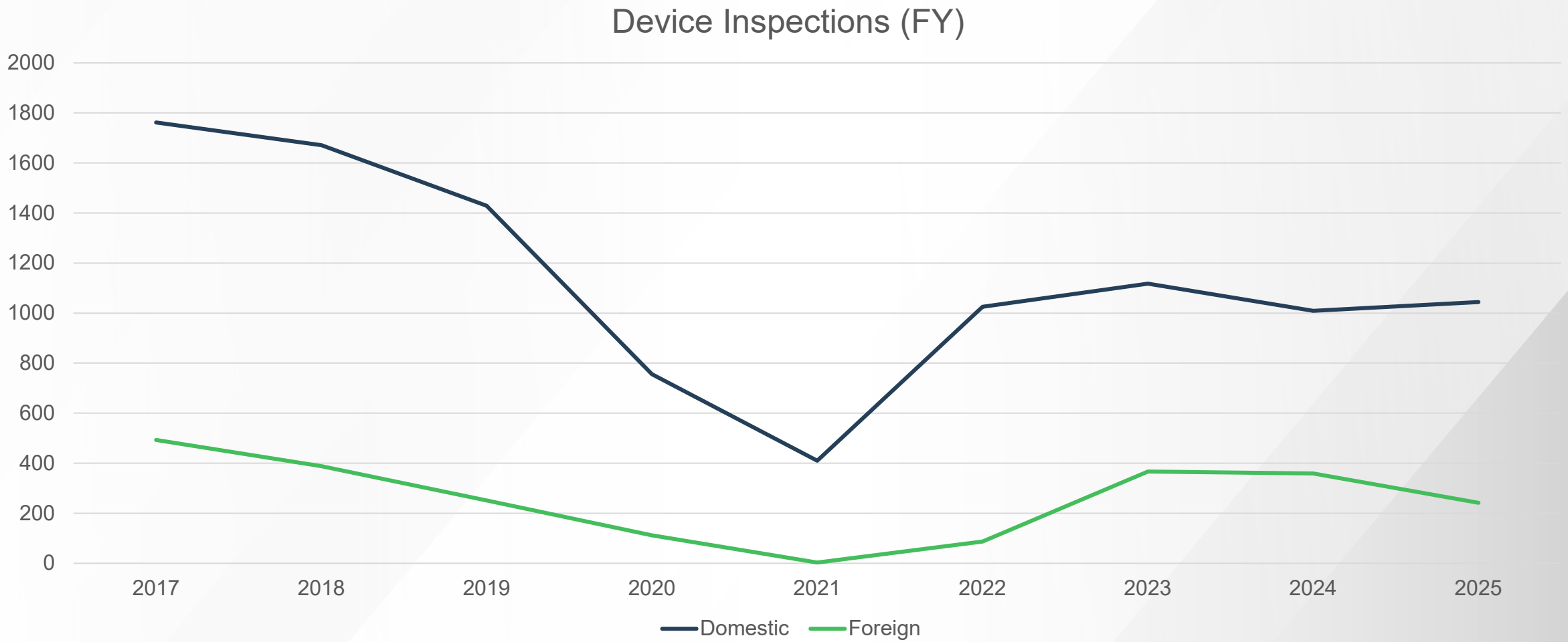
# Recalls: Predictions

- **Increased Use of FDA's Communications Platforms**
  - Initial post of recall action in FDA's Medical Device Recall Database; updated after classification
  - FDA will post a company's press release about a recall, market withdrawal, or safety alert
  - FDA also can post its own press release about a product recall - Safety Communication and Early Alert system
  - Recalls monitored by FDA will be published in the weekly Enforcement Report, available electronically
- **Enhanced Coordination Between District Offices and Within CDRH**
  - FDA recall coordinators are located in "Inspectorates" across the country – 4 Medical Device Inspectorates in the US (Midwest, Northeast, South, West)
  - Office of Product Evaluation and Quality coordinates the stakeholders within CDRH
    - Classify the recall, request revisions to the customer notification about the recall or the corrective action to address the underlying issue, and monitor the status of the recall activities

# Inspections: Developments

- **Top 5 Citations (FY2025)**
  - CAPA (25.4%)
  - Complaints (19.8%)
  - Purchasing Controls (10.7%)
  - Nonconforming product (8.8%)
  - Process Validation (7.4%)
- **Unannounced Foreign Inspections**
  - Following EO 14293, FDA announced in May 2025 that it would increase the frequency of unannounced inspections at foreign facilities
- **Use of Remote Regulatory Assessments (Q&A issued June 2025)**
  - Q&A Guidance updated from 2024
  - Does not appear to be as often used for medical device firms as for with drug firms

# Inspections: Trends




**Fewer Domestic Inspections Post-COVID**

# Inspections: Predictions

- **OII Reorganization**
  - FDA will merge all its medical product and clinical research inspectorates
  - More generalists, less subject matter expertise
  - Reverses 2017 effort to do the inverse
- **QMSR**
  - By Feb. 2, 2026, manufacturers need to have established procedures that comply with new QMSR requirements
  - ISO 13485 harmonization + select QSR requirements
  - Key areas of focus for FDA will be incorporating risk-based decision-making throughout QMS and supplier controls

# Warning Letters and Enforcement

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# Warning Letters: Developments

- **Top Citations in 2025**
  - CAPA (820.100)
  - Complaint Handling (820.198)
  - Purchasing (820.50)
  - Process Validation (820.75)
  - Medical Device Reporting (803.17)
  - Unique Device Identifier (830.300)

# Warning Letters: Developments

- **DRG Instruments (3/31/25)**
  - RUO-labeled assay intended for clinical use
  - Customer certification insufficient to cure issue (FDA notes one customer did not sign)
  - FDA's "review of these customers' websites strongly suggests that these customers are engaged in clinical diagnostic testing"

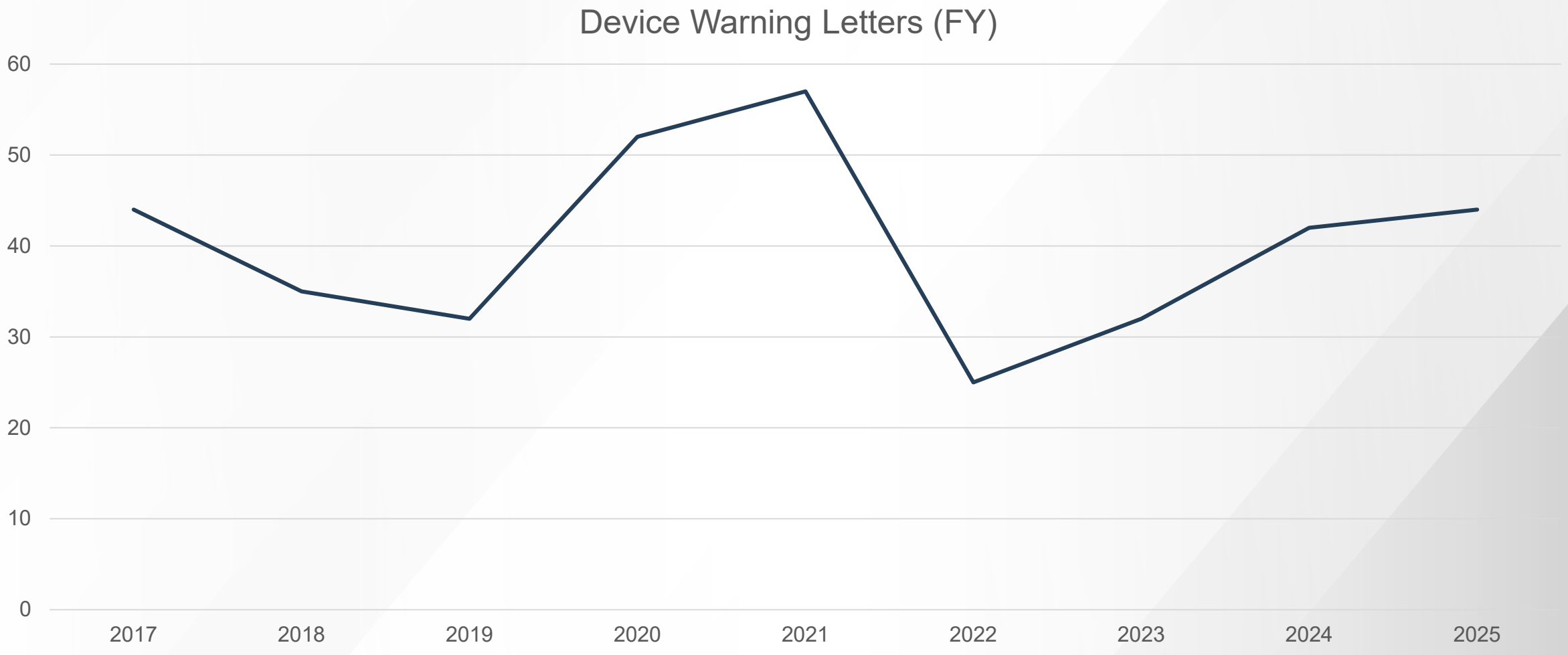
- **Visgeneer, Inc (6/13/25)**
  - eBchek Blood Glucose Monitoring System and eBuricacid/Uritouch Blood Uric acid Monitoring System
  - Design control deficiencies, validation data does not match 510(k) submission, changes not assessed for new 510(k)
  - Even though product no longer marketed after FDA said new 510(k) needed, did not conduct a recall
  - Import alert to refuse all product until WL remedied

# Warning Letters: Developments

- **Exer Labs, Inc. (2/10/25) & SeniorLife Technologies (8/21/25)**
  - AI software that analyzes patient movement to diagnose musculoskeletal and neurological disorders
  - Listed under 21 CFR 890.5360 Measuring Exercise Equipment as 510(k) exempt
  - FDA found both exceed .9 limitations

- **WHOOP, Inc. (7/14/25)**
  - Wearable “blood pressure insights” – daily systolic and diastolic blood pressure estimates
  - Positioned as general wellness
  - FDA’s states BP measurement is “inherently associated with the diagnosis of hypo- and hypertension and is therefore intended for use in the diagnosis of a disease or other condition, or in the cure, mitigation, treatment, or prevention of disease”

# Warning Letters: Trends




**Minor Fluctuations**

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# Warning Letters: Predictions

- **Longer Letters, More Citations**
  - Ease of digital document requests and review
  - Potential use of AI for review and drafting
- **More Foreign Warning Letters**
  - Increased frequency of unannounced foreign inspections and focus on data integrity may increase share of warning letters to foreign facilities
- **Use of AI to Generate More Warning Letters Overall**
  - CDER used AI to identify violations and issue a large bolus of Warning Letters regarding prescription drug direct-to-consumer advertising
  - Likelihood that these AI tools will be used by CDRH for similar surveillance and identification of violations

# Enforcement: Developments and Predictions

- **Import Alerts**
  - Likely to be an increase in the number of Import Alerts detaining foreign devices, including components
  - Protect impact on supply chain
- **DOJ Changes**
  - May 12, 2025 Criminal Division memo, FD&C Act remains a priority area of enforcement
  - Reorganization of DOJ Consumer Protection Branch
- **Novel Uses of the False Claims Act**
  - Illumina settled with DOJ for $9.8M
  - Alleged FCA claims related to cybersecurity *vulnerabilities* in genomic sequencing systems
  - Focused on deficient process/design, not actual breach

### CDRH Enforcement Priorities

- Risk-based enforcement
- Repeat OAI firms
- Unapproved device enforcement
- Data Integrity/Quality
- Unique Device Identifier
- Surveillance activities

# Legislation, Rulemaking and Guidance Documents

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# Legislation and Rulemaking: Developments

- **LDT Rule**
  - U.S. District Court vacated rule (3/31/25)
  - FDA final rule reverting 21 C.F.R. § 809.3 to prior language (9/19/25)
  - Questions remain: e.g., definition of LDT, components, CDx
  - Seemingly no proposed legislation (VALID Act)
- **IVD Reclassifications**
  - Class III → II
  - **Final**: Hep B Assays (9/18/25)
  - **Proposed**: In situ hybridization (ISH) test systems (6/11/25) and nucleic acid-based test systems (11/25/25), each indicated for use with a corresponding approved oncology therapeutic product

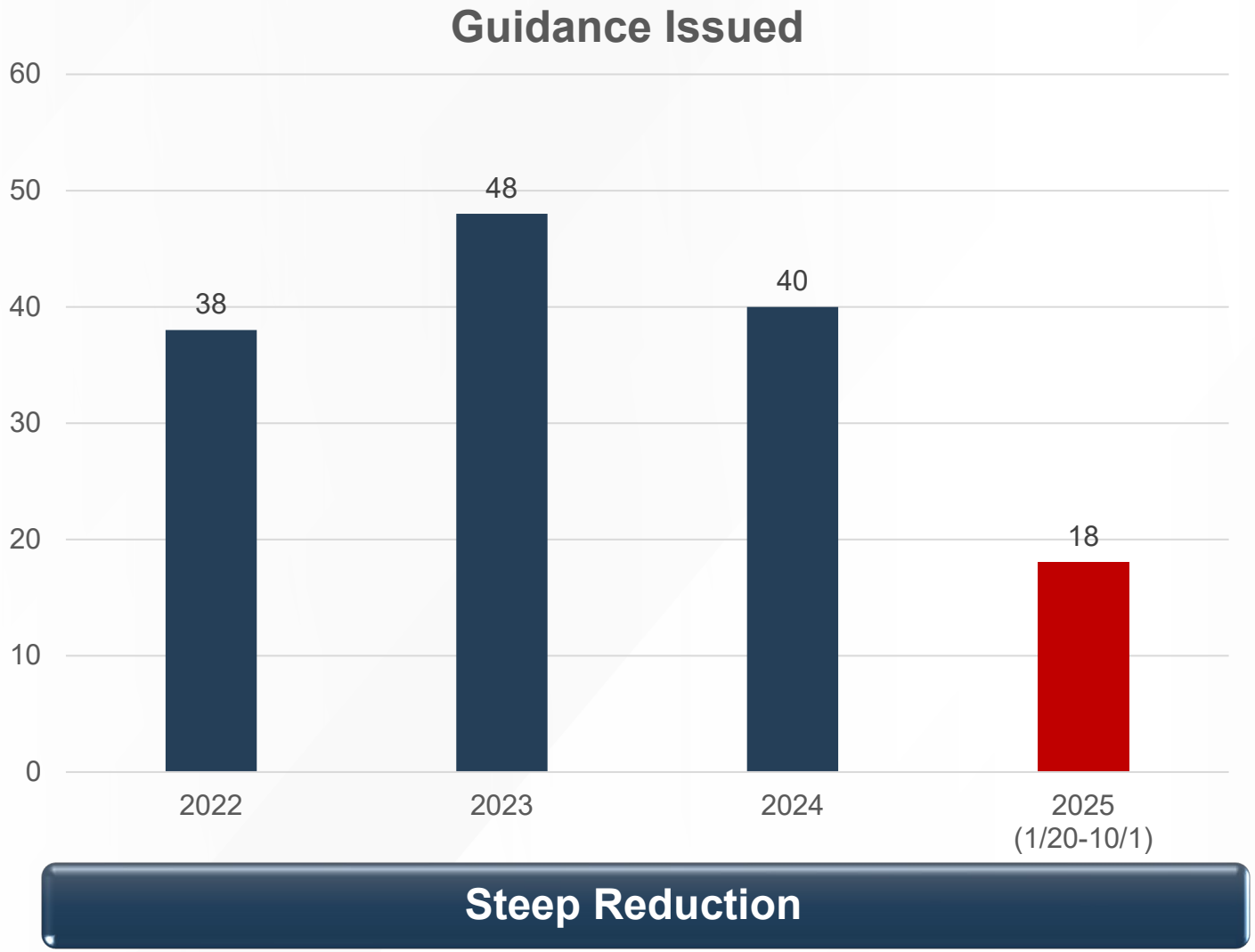
# Legislation and Rulemaking: Predictions

- **"Unified Agenda" Spring 2025**
  - Reclassification of unclassified wound dressings/washes containing antimicrobials or other chemicals (proposed 11/30/23) – Class III for medically important antimicrobials
  - No Unified Agenda for 2026 yet
- **MDUFA VI Underway**
  - FDA held first meeting August 2025, kicking off negotiations
  - New bill needs to be passed by September 30, 2027
- **BIOSECURE Act Reintroduced**
  - Restricts the use of certain biotechnology equipment and services from biotechnology companies of concern in performance of federal contracts or grants
  - Passed in Senate NDAA (10/9/25); House originally omitted, but revised NDAA text includes it (12/8/25)
  - Revised from last year's version that did not pass
    - In addition to OMB mechanism to identify BCOCs, DOD's 1260H list added
    - WuXi not currently named, although multiple processes by which they could be added
    - Mass spectrometry and PCR machines omitted from scope
    - Struck "has reason to know" – FCA scienter

# CDRH Guidance (2025)

| | |
|---|---|
| eCopy Program for Medical Device Submissions | Transfer of a Premarket Notification (510(k)) Clearance – Questions and Answers: (Draft) |
| Cross-Center Master Files: Where to Submit (Draft) | Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program |
| Menstrual Products - Performance Testing and Labeling Recommendations: (Draft) | Electronic Submission Template for Medical Device Q-Submissions: (Draft) |
| Quality Management System Information for Certain Premarket Submission Reviews: (Draft) | Evaluation of Sex-Specific Data in Medical Device Clinical Studies |
| Computer Software Assurance for Production and Quality System Software | Institutional Review Board (IRB) Written Procedures |
| Consideration of Enforcement Policies for In Vitro Diagnostic Tests During a Section 564 Declared Emergency | Premarket Approval Application and Humanitarian Device Exemption Modular Review |
| Animal Studies for Dental Bone Grafting Material Devices - Premarket Notification (510(k)) Submissions | Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act |
| Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions | Pulse Oximeters for Medical Purposes - Non-Clinical and Clinical Performance Testing, Labeling, and Premarket Submission Recommendations: (Draft) |
| Medical Device User Fee Small Business Qualification and Determination | Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations: (Draft) |
| Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions | Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers |
| Unique Device Identifier Requirements for Combination Products: (Draft) | Validation of Certain In Vitro Diagnostic Devices for Emerging Pathogens During a Section 564 Declared Emergency: (Draft) |
| Conducting Remote Regulatory Assessments Questions and Answers | Study of Sex Differences in the Clinical Evaluation of Medical Products |
| Hernia Mesh – Package Labeling Recommendations: (Draft) | |

# CDRH Guidance: Trends and Predictions




## Why?

- Initial regulatory freeze
- "10-to-1" rule (some guidance marked as "deregulatory" and therefore exempt)
- Agency turnover / RIFs

## Yes but…

- CDRH Proposed Guidances
  - FY2026: 21
  - FY2025: 29

# Staffing and Shutdown Impacts

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# Staffing

## Impact of Agency RIFs/Turnover

- Early acute issues mitigated by some termination reversals
- No widespread reports of application review delays
- Leadership relatively stable at CDRH compared to CDER/CBER
- Personal experience:
  - Some Offices/Divisions will no longer schedule Q-sub meetings until after written feedback and confirmation that meeting still desired
  - Shortage of statistical review staff led to delay in scheduling SIR
  - Recall could not be closed despite agency determination that it was warranted
  - Other informal feedback could not be provided due to general resource constraints

# Shutdown

## Continued Activities

- During shutdown, ~86% of FDA staff remained at work
- Review of pending applications where user fee has already been paid (510(k), de novo, PMA)
- Review of pre-sub requests and IDEs (new or pending) – do not require user fees but are considered part of the user-fee agreement (may not get in-person meetings)
- Critical safety functions – recalls, shortages, MDRs, for-cause inspections, import screenings

## Paused Activities

- New submissions that require user fees that cannot be processed
- Routine inspections

**Continuing resolution only funds the government through January 30, 2026**

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