FDA Policies: Reflecting on the Past, Understanding the Present, and Preparing for the Future – Medical Device Regulatory Intelligence in a Changing Landscape

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Agenda

Part 1: Reflecting on the Past

- Historic FDA policy milestones shaping today's device framework
- Drivers of increased regulatory actions, including post-pandemic shifts
- Connections between policy changes & and device priorities

Part 2: Understanding the Present

- Current enforcement focus areas for devices, including facility inspections & priorities
- Impacts of AI, cybersecurity, and supply chain requirements on medical devices
- Real examples from recent device-related actions

Part 3: Preparing for the Future

- QMSR transition timeline and implementation for device compliance
- Emerging guidance on AI, real-world evidence, and cybersecurity
- Building your 90-day action plan to navigate changes

Q&A: Your Questions

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Policy Context & Device Impact

Current Administration Priorities

- Make America Healthy Again (MAHA) - food/nutrition focus (EO 14212 issued February 13, 2025; May 2025 report on chronic diseases)
- Domestic manufacturing emphasis (reducing foreign reliance through supply chain resilience)
- Supply chain resilience (phasing out petroleum-based materials; promoting U.S.-based production)
- Healthcare cost reduction (via chronic disease prevention, indirectly supporting wearables and monitoring devices)

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Policy Context & Device Impact

Device-Related FDA Activities:

- Material safety scrutiny (e.g., phasing out synthetic dyes in foods and medications)
- Supply chain documentation requirements (enhanced visibility for multi-tier suppliers)
- Foreign facility oversight (increased unannounced inspections announced May 2025)
- Quality system expectations (alignment with risk-based approaches under QMSR)

Import Enforcement:

- Import Alert for QSR violations (active for surveillance of foreign-listed devices)
- Import Alert for detention of devices without 510(k) clearance (focus on unapproved imports)

The Practical Impact: Device manufacturers face increased scrutiny across multiple fronts, including potential extensions of MAHA principles to device materials and supply chains .

The Enforcement Evolution

Recent Device-Related Events (From Import Data):

Recall impacts on respiratory devices (high refusals for catheters and endoscopes)

Supply chain disruptions (elevated refusals in production-related codes from Asia)

Vulnerabilities in connected devices (refusals for unsafe or misbranded tech products)

Quality system failures (recurring QSR violations leading to adulteration charges)

Current Enforcement Environment (FY2019-2024 Import Data)

3,500

Increased Refusals: ~3,500 refused lines for devices in FY2024 (up ~10% from FY2023; total lines ~20M+ across years)

10,000

Examined/Sampled Lines: ~10,000 examined, ~500 sampled in FY2024, focusing on high-risk imports

1,082

Foreign Focus: Significant increase in refusals from Asia (e.g., China ~1,082 refused lines in FY2024, India ~75)

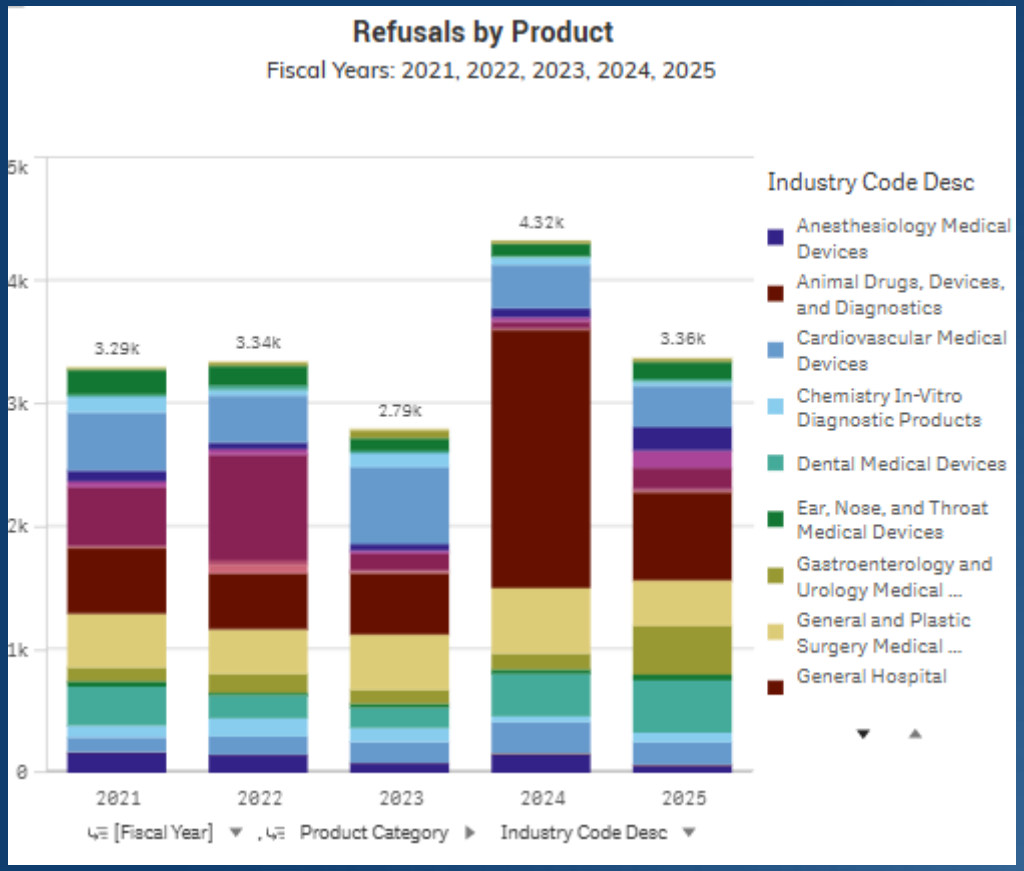
30-90

Enforcement Timelines: Refusals processed within average 30-90 days based on dates

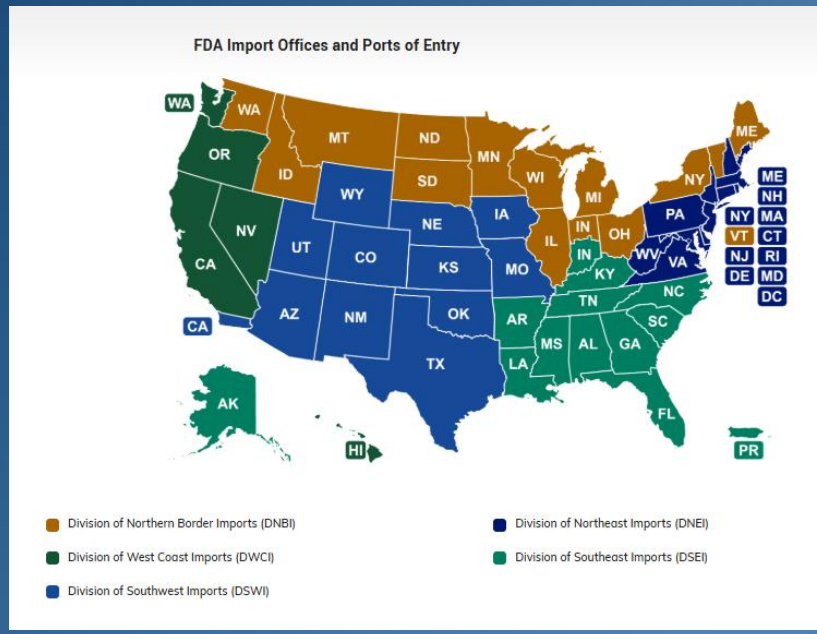
What is Different Now:

- Converging initiatives (e.g., risk-based import scrutiny)
- Technology-enabled oversight (e.g., citations for unsafe digital devices)
- Global coordination (e.g., higher refusals from key exporting regions)

Import Refusals



Import Divisions*	
Division of Northeast Imports 788	Division of Northern Border Imports 1,603
Division of Southeast Imports 10,831	Division of Southwest Imports 1,769
Division of West Coast Imports 2,108	



[FDA Dashboards - Import Refusals]

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Observable Trends

TREND ONE
Import & Supply Chain Focus

- Foreign facility inspections increasing (65% rise in foreign inspections FY2024 per CDRH reports)
- Supply chain documentation requirements expanding (e.g., SBOM for cybersecurity; multi-tier visibility under MAHA influences)

TREND TWO
Technology Requirements

- AI/ML guidance development (Jan 2025 draft on lifecycle management)
- Cybersecurity expectations (June 2025 final guidance emphasizing threat modeling)
- Software validation scrutiny (integrated into design controls in 483 observations)

TREND THREE
Quality System Evolution

- Risk-based approaches (harmonization with ISO 13485 under QMSR)
- Post-market integration (enhanced MDR and complaint handling)
- Predictive quality expectations (use of real-world evidence in submissions)

What This Means: Prepare for comprehensive oversight across all areas, with technology and global supply chains as key risk vectors

Current Enforcement Landscape

Enforcement Activity Observations (FY2019-2024 Import Data):

- **Refusal Trends:** ~3,500 refused lines in FY2024 (top charges: Adulterated ~1,000, Unregistered ~1,500, Misbranded ~500)
- **Observation Patterns:** High focus on product codes like gloves (80LYZ refusals ~477), catheters (80FMI ~2780), endoscopes (78FGB ~2780)
- **Import Frequency:** ~20M+ total lines in FY2024, with ~10,000 examined

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Current Enforcement Landscape
Geographic patterns

- **Domestic vs. Foreign:** Foreign sources ~90% of refusals (e.g., Asia ~80% of total refused lines)
- **Country-by-Country Distribution:** Concentrations from China (~1,082 refused), India (~75), Pakistan (~44)
- **Region-Specific Focus:** Increased scrutiny on Asia for quality/adulteration charges (e.g., ~2,000 refused lines combined)
- **The Message:** FDA enforcement is active and expanding, with persistent concentration on scrutinizing foreign manufacturers.

Timeline of Key Developments

Recent Regulatory Developments

JAN. 7, 2025

AI/ML regulatory development: Draft guidance on lifecycle management issued

JUNE 26, 2025

Cybersecurity guidance evolution: Final guidance issued (replaces October 2023 version)

FEB. 2, 2026

QMSR announcement: Final rule published February 2, 2024; effective February 2, 2026

LDT regulation changes: Enforcement discretion adjustments in FY2025 guidance

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Timeline of Key Developments
Acceleration pattern

- Shorter time between guidance and enforcement (e.g., cybersecurity citations within months of 2025 finalization)
- Concurrent development of multiple requirements (e.g., AI and cybersecurity overlapping with QMSR)
- Global harmonization efforts (e.g., ISO 13485 alignment by 2026)

Looking Forward: Expect continued rapid evolution, with FY2025 guidance driving near-term actions

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Three Priority Areas

- Design/Production Expectations (high refusals for catheters/endoscopes; charges like 2780 for no 510(k))
- CAPA/Control Effectiveness (common in adulteration charges ~1,000 across data)
- Risk Management Integration (emerging in unsafe/misbranded refusals ~500)

- Current Requirements (refusals for unsafe tech devices, e.g., code 508 ~500)
- Documentation Expectations (premarket issues in misbranded charges)
- Future Requirements (enhanced for connected imports; no-breach citations inferred from patterns)

- Visibility Requirements (multi-tier issues in foreign refusals, e.g., Asia ~80%)
- Supplier Qualification (audits emphasized in adulteration charges)
- Change Control (monitoring for disruptions, e.g., glove/catheter codes)

Enforcement Patterns

Common Citations (FY2019-2024 Data):

- Design Controls (highest in FY2024 refusals, e.g., code 2780 ~2,780 for no clearance)
- CAPA Systems (prevalent in ~40% of charges, e.g., adulterated code 118 ~1,000)
- Production Controls (recurring in quality violations, code 508 ~500)
- Documentation Issues (e.g., incomplete records in ~30% of cases, code 341 ~500)

By Device Classification:

- Class I Devices: ~15% of refusals (over-represented, e.g., spectacles, gloves)
- Class II Devices: ~67% of refusals (majority, including catheters)
- Class III Devices: ~18% of refusals (proportional, e.g., endoscopes)

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Enforcement patterns
Geographic Distribution

Domestic Patterns:
Clustered in U.S. states (e.g., CA ~25%, TX ~15%)

Foreign Manufacturer Focus:
~90% of refusals, with emphasis on Asia (e.g., China ~1,082, India ~75)

Inspection Observations

Top 483 Categories (FY2019-2024 Data):

- Quality System Procedures (broad non-compliance, e.g., adulteration code 118 ~1,00
- Design Control Requirements (e.g., validation failures, code 2780 ~2,780)
- Production and Process Controls (consistency issues, code 508 ~500)
- Misbranding (labeling failures, code 341 ~500)

Evolution in Focus:

- Traditional vs. Current Expectations: Shift from basic compliance to predictive and technology-integrated systems
- New Areas of Scrutiny: Safety in tech devices (code 508 rising)
- Technology-Related Citations: Increasing in software and connected devices

Preparation Priorities: Focus on areas with highest citation rates, such as design and production, through mock audits

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Import Enforcement

Refusal Charges:

- Adulterated (code 118 ~1,000),
- Unregistered (3280 ~1,500),
- Misbranded (341 ~500)

Patterns - Products affected include:

- Gloves (code 80LYZ ~477 refusals)
- Catheters (80FMI ~2,780)
- Endoscopes (78FGB ~2,780)

- Products Affected: High-volume items like administration sets, needles
- Geographic Focus: Primarily Asia (China ~1,082 refused, India ~75, Pakistan ~44)
- Resolution Timelines: Avg 30-90 days based on refused dates

- Documentation Requirements (ensure registration, labeling compliance)
- Supplier Qualification (audits for high-risk regions)
- Compliance Verification (pre-shipment reviews)

New Import System Impact: Nationalized Entry Review Program (2025) centralizes reviews using PREDICT AI for risk-targeting, speeding low-risk clearances but intensifying high-risk enforcement, timelines, and supply chain scrutiny for devices.

AI/ML Device Regulation

Current State

- FDA-authorized AI devices: Over 691 (as of July 2025; primarily in radiology at 76%)
- Primary therapeutic areas: Radiology, cardiology, neurology
- Regulatory pathways used: Mostly 510(k) for Class II; De Novo for novel

Regulatory Framework

- Current guidance documents: January 2025 draft on lifecycle management and marketing submissions
- PCCP requirements: Predetermined Change Control Plans for algorithm modifications
- Performance monitoring expectations: Bias assessment, real-world data post-market

Preparation Needs

- Algorithm documentation (training data transparency)
- Change control planning (PCCP integration)
- Performance monitoring systems (ongoing validation)

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Cybersecurity Requirements

Current Requirements:

- Threat modeling (identify and mitigate risks)
- Software bill of materials (SBOM for components)
- Vulnerability management (disclosure and patching)
- Update mechanisms (secure over-the-air updates)

Enforcement Status:

- Inspection focus areas: Documentation and architecture (citations in FY2025 483s)
- Common citations: Lack of SBOM or threat models (no breach required)
- Timeline for compliance: Effective June 26, 2025; grace period ended March 2024 for prior guidance

Future Direction: Enhanced requirements expected, with focus on performance testing

QMSR Transition

Major Changes

- Alignment with ISO 13485:2016 (risk-based quality management)
- Risk-based approach (emphasis on hazard analysis)
- Management responsibility expansion (top-level accountability)
- Documentation requirements (streamlined but retained FDA specifics like MDR)

Preparation Timeline

- Gap analysis phase (assess current QSR vs. ISO)
- Implementation phase (update procedures by mid-2025)
- Verification phase (internal audits before 2026)

Key Date: Effective February 2, 2026

Strategic Opportunity: Global harmonization benefits (one system for multiple markets via MDSAP)

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510(K) Program Updates

Current Challenges:

- RTA rates: Increased to 23% in FY2025 (due to incomplete submissions)
- Review timelines: Average 90 days, but extended for complex (e.g., AI) devices
- Predicate selection: Scrutiny on older predicates (10-year limit trends)
- Performance data requirements: Emphasis on clinical and real-world evidence

Available Pathways:

- Traditional 510(k) (full equivalence demonstration)
- Special 510(k) (minor changes to cleared devices)
- Abbreviated 510(k) (conformance to standards)
- De Novo (novel low/moderate risk devices)

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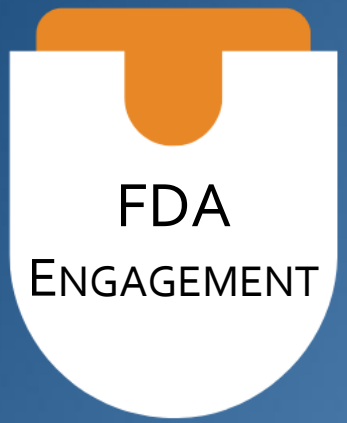
510(k) Program Updates
Success Strategies

Match to device risk/complexity

Pre-sub meetings recommended



Q-Subs for feedback; 15% better approval rates

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Upcoming Guidance

Published Priorities:

A-LIST GUIDANCES

Artificial Intelligence-Enabled Device Software Functions; Predetermined Change Control Plans; Real-World Evidence in Submissions; Laboratory Developed Tests enforcement

B-LIST GUIDANCES

Nitinol device testing; Patient engagement in development (resources permitting)

UNDER DEVELOPMENT

Evaluation of Thermal Effects of Medical Devices; Cybersecurity updates

Impact Areas:

DEVICES AFFECTED

AI/ML, software, high-risk implants

TIMELINE EXPECTATIONS

A-list targeted for FY2025 publication; enforcement 12-18 months post

PREPARATION NEEDS

Treat drafts as actionable; integrate into QMS

Risk Assessment Framework

Factors to Consider:

- Inspection history (past 483s or warnings)
- Product risk level (Class I-III classification)
- Compliance status (QSR/ISO gaps)
- Market actions (recalls or complaints)
- Geographic location (foreign vs. domestic scrutiny)

Risk Mitigation:

- Quality system improvements (CAPA enhancements)
- Documentation updates (SBOM, PCCP)
- Training programs (on cybersecurity and AI)
- Monitoring systems (real-time trend analysis)

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Building Resilience

Strategic Priorities:

SYSTEM MODERNIZATION

- Digital quality systems (automated CAPA tracking)
- Data analytics (predictive risk tools)
- Automated monitoring (post-market surveillance)

REGULATORY ENGAGEMENT

- FDA meetings (Q-Subs, TAP pilot for breakthroughs)
- Submission strategy (pathway optimization)
- Program participation (MDSAP for inspections)

GLOBAL APPROACH

- Harmonized systems (QMSR/ISO alignment)
- International standards (IMDRF collaboration)
- Multi-market strategy (reduced redundancy

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Your 90 Day Plan

Days 1-30 Access

- Current compliance status (review warning letters/483s)
- Risk areas (e.g., cybersecurity gaps)
- Resource needs (training for QMSR)
- Priority gaps (AI documentation)

Days 31-60 Implement

- Critical corrections (CAPA updates)
- System updates (ISO alignment)
- Training programs (staff on new guidance)
- Documentation improvements (SBOM development)

Days 61-90 Prepare

- Future requirements (QMSR mock audits)
- Monitoring systems (real-world data tools)
- Response procedures (483 handling templates)
- Continuous improvement (metrics tracking

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Resources and Support

FDA Resources:

- Guidance documents (CDRH website, FY2025 lists)
- CDRH Learn (training modules on QMSR, AI)
- Database access (warning letters, 483s dashboard)
- Public meetings (webinars on MAHA impacts)

Industry Resources:

- Trade associations (AdvaMed, MDMA for policy updates)
- Training programs (RAPS convergence toolkit)
- Consultants (for gap analyses)
- Peer networks (forums on enforcement trends)

Internal Resources:

- Quality systems (internal audit teams)
- Regulatory intelligence (subscription to FDA alerts)
- Training programs (customized for device class)
- Management support (executive buy-in for transitions)

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Critical Takeaways

1. Enforcement is intensifying (~3,500 refusals in FY2024)
2. Requirements are evolving rapidly (e.g., QMSR by 2026, AI/cyber guidance in 2025)
3. Technology is central to compliance (high refusals for tech devices)
4. Global harmonization offers opportunities (ISO alignment reduces burdens)
5. Proactive preparation is essential (address foreign scrutiny and supply chains)

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Your Next Steps

Assess your current state (gap analysis)

Identify priority gaps (CAPA, design)

Develop action plan (90-day framework)

Execute systematically (monitor trends)

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Upcoming Trainings

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Q&A

Discussion Topics:

- Your specific challenges (e.g., QMSR transition for Class II devices)
- Implementation strategies (cybersecurity documentation)
- Resource priorities (AI training)
- Timeline concerns (import alert resolutions)

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