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Quarterly Medical Device Warning Letters Update: January – March 2026

May 15, 2026

Medical Devices and Diagnostics

This client alert summarizes trends and otherwise notable allegations in publicly available FDA warning letters relating to medical devices. This alert summarizes trends in the warning letters issued in the first quarter of 2026 (January through March).[1]

As of May 15, 2026, FDA posted fourteen warning letters that were issued in the first quarter of 2026 alleging violations of the Food, Drug, and Cosmetic Act (FDCA) related to medical devices.[2] Three letters issued in 2025 were posted, as well. Key trends and notable allegations in warning letters this quarter include:

1. **Most Commonly Cited Violations**: Eleven of the seventeen letters allege violations of the quality system regulations (QSR). The most commonly alleged QSR violation related to corrective and preventive action (CAPA) (21 CFR 820.100), which was cited in nine letters. Design control (21 CFR 820.30) violations were alleged in seven letters, and alleged violations of requirements for process validation (21 CFR 820.75), nonconforming product (21 CFR 820.90), and complaint files (21 CFR 820.198) were cited in six letters each.

   The letters issued after February 2, 2026, acknowledge that the Quality Management System Regulation (QMSR) has gone into effect, but FDA states that the applicable inspections had been conducted under the QSR. Notwithstanding that these warning letters allege violations of the QSR, FDA states that corrective actions must be proposed and implemented pursuant to the QMSR.

[1] This alert summarizes some of the allegations contained in FDA's letters. It does not contain any analyses, opinions, characterizations, or conclusions by Covington & Burling LLP. The information presented herein does not necessarily reflect the views of Covington & Burling LLP or any of its clients.

[2] These warning letters include only those that were publicly posted by FDA as of the date listed, including: CMS #711080 (Sept. 3, 2025), CMS #717394 (Nov. 12, 2025), CMS #720250 (Dec. 19, 2025), CMS #719428 (Jan. 8, 2026), CMS #720529 (Jan. 8, 2026), CMS #720554 (Jan. 8, 2026), CMS #720555 (Jan. 9, 2026), CMS #722046 (Jan. 23, 2026), CMS #722180 (Jan. 27, 2026), CMS #717927 (Jan. 28, 2026), CMS #719460 (Jan. 29, 2026), CMS #715068 (Feb. 6, 2026), CMS #720762 (Feb. 10, 2026), CMS #723370 (Feb. 24, 2026), CMS #721702 (Feb. 26, 2026), CMS #720527 (Mar. 17, 2026), and CMS #723866 (Mar. 25, 2026). Late posted letters will be addressed in a future client alert.

2. **Concerns Regarding Human Use of Non-Device Product**: In a warning letter to Physitemp Instruments, LLC, FDA raises concerns regarding the sterilization validation for implantable temperature monitoring probes that arguably are not devices. FDA acknowledges the company's response that the probes are not subject to such validation requirements because they "are primarily used in general laboratory research applications … and not human use," but the Agency still asserts that the company failed to assess whether additional actions were needed to address the risk that the products could be used in humans "due to ambiguous labeling." FDA further implies that the company knew (or should have known) that the probes were used on humans based on a complaint that requested a replacement probe because "patients" were coming.

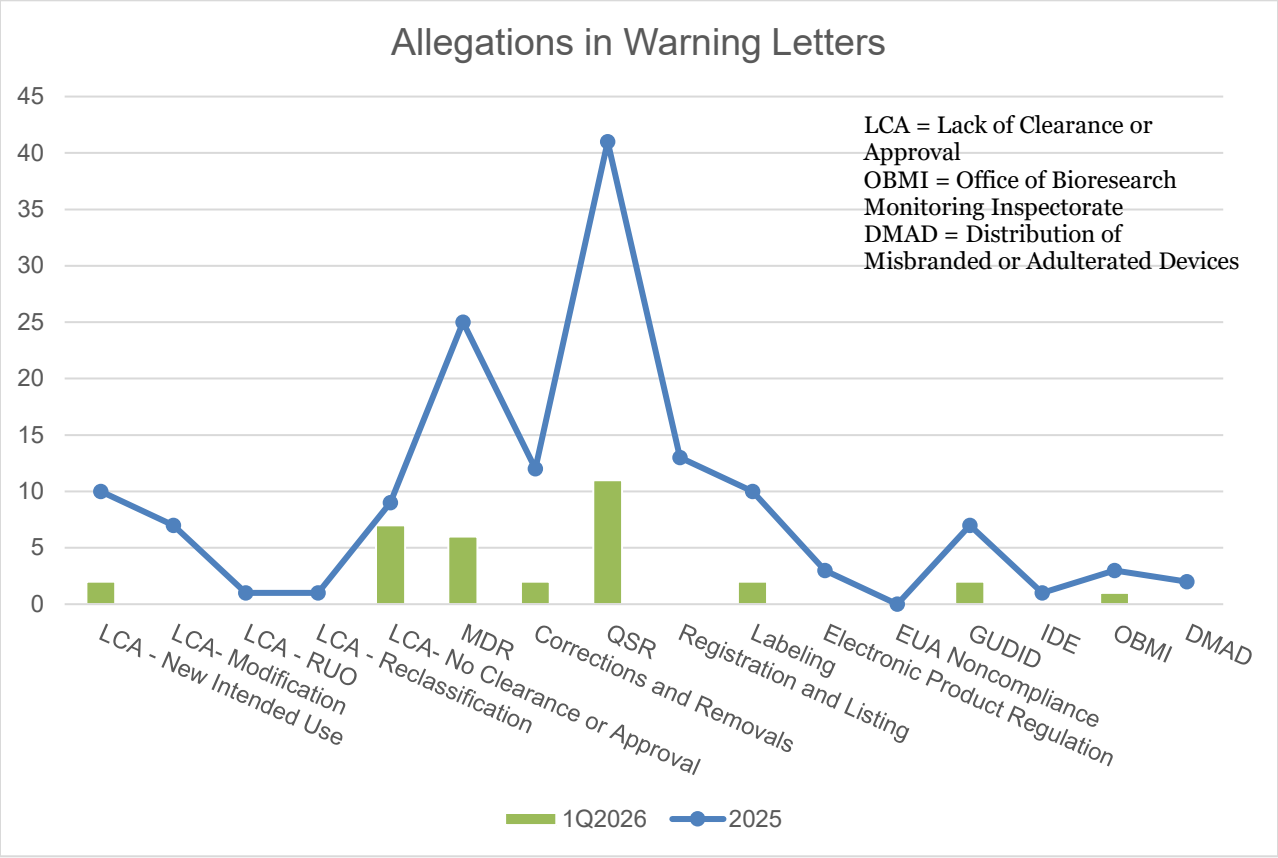
   The warning letter does not directly allege that the probes are devices. Rather, FDA concludes that premarket authorization "will be required **if** the intended use … is expanded to human use" (emphasis added). If FDA has not concluded that such products are devices, however, it is unclear why they warranted discussion in the warning letter.

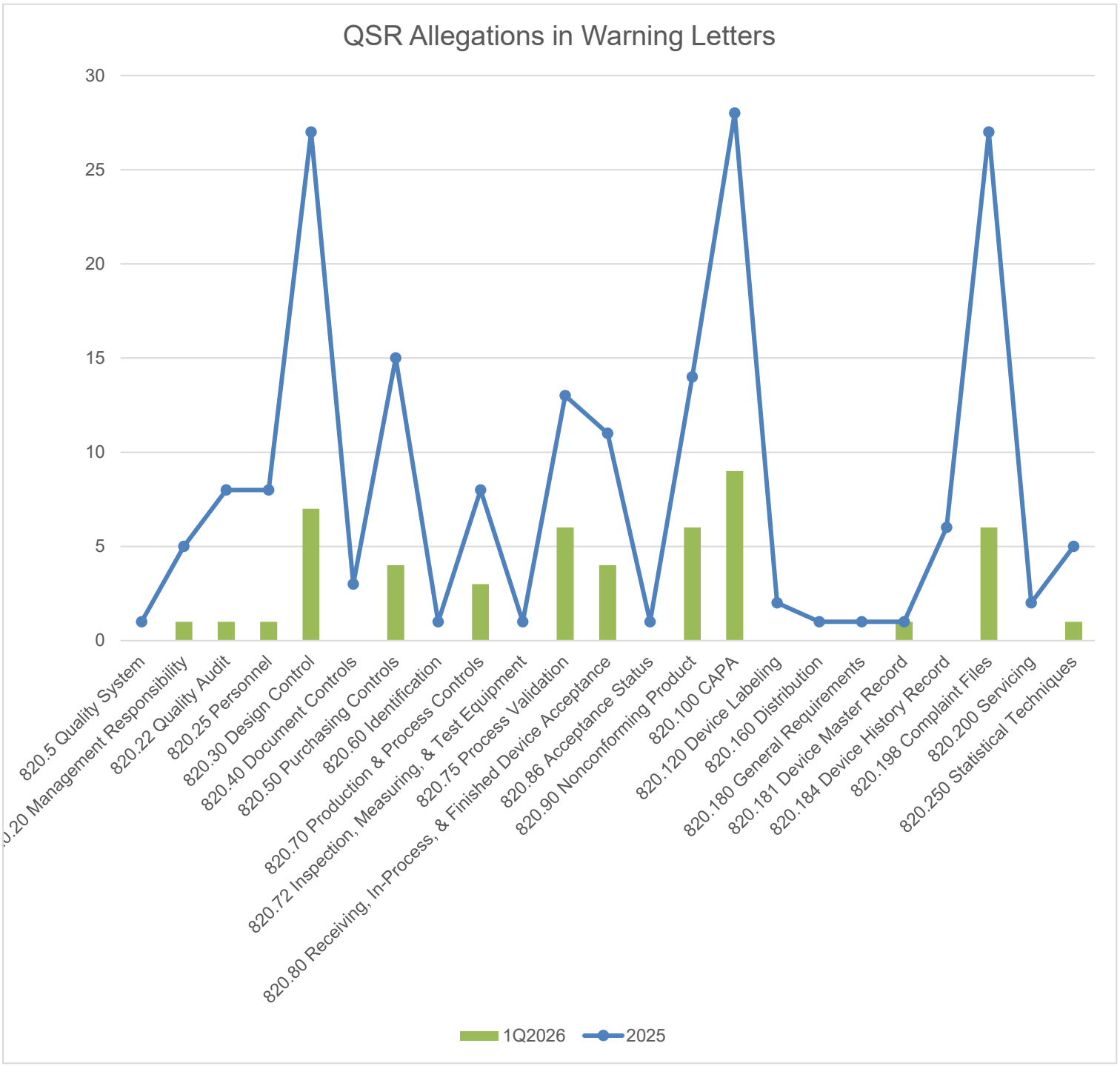
3. **Concerns Regarding Expanded Use of Human Device for Use in Animals:** FDA's device authority extends to articles used for the diagnosis of diseases and conditions "in man or other animals," but FDA does not actively regulate animal devices in the same way that the Agency regulates human devices. While FDA can take action if an animal device is misbranded or adulterated, the Agency does not require premarket approval for devices intended for animal use. In a warning letter to Longhorn Vaccines and Diagnostics LLC, however, FDA alleges that the company's device lacked clearance or approval for new intended uses, including a use in animals.

   Specifically, the Agency alleges that evidence of "major changes or modifications to … intended use" of the company's device includes a website statement about the USDA expanding its use of the device "beyond SARS-CoV-2 and African Swine Fever to facilitate the tracking and surveillance of the avian influenza strain that is infecting wild bird populations and US poultry flocks." The company's device was de novo authorized only for use with certain human specimens suspected of containing Influenza A virus RNA or Mycobacterium tuberculosis DNA. Accordingly, use with specimens suspected of containing SARS-CoV-2, African Swine Fever, or avian influenza would be new intended uses. Their use in animals, however, would not require premarket review. Nonetheless, FDA alleges that the new intended uses could significantly affect the safety and effectiveness of the device, including "risks to the user handling clinical specimens without appropriate precautions for the specific pathogen."

4. **HIV Self-Collection Kits**: FDA issued five warning letters underscoring its continued position that at-home dried blood spot (DBS) self-collection kits for HIV testing are devices that require FDA clearance or approval, even when distributed by or in connection with a laboratory performing a laboratory developed test (LDT). Consistent with FDA's October 2024 public safety communication and prior warning letter regarding HIV DBS kits, these actions reflect FDA's position that specimen collection kits are standalone medical devices subject to FDA jurisdiction and signals that FDA may pursue enforcement where uncleared or unapproved HIV self-collection kits are distributed.

The allegations in the warning letters sent this quarter can be grouped into the following categories:




QSR Allegations in Warning Letters
30
25
20
15
10
5
0
820.5 Quality System
.20 Management Responsibility
820.22 Quality Audit
820.25 Personnel
820.30 Design Control
820.40 Document Controls
820.50 Purchasing Controls
820.60 Identification
820.70 Production & Process Controls
820.72 Inspection, Measuring, & Test Equipment
820.75 Process Validation
820.80 Receiving, In-Process, & Finished Device Acceptance
820.86 Acceptance Status
820.90 Nonconforming Product
820.100 CAPA
820.120 Device Labeling
820.160 Distribution
820.180 General Requirements
820.181 Device Master Record
820.184 Device History Record
820.198 Complaint Files
820.200 Servicing
820.250 Statistical Techniques
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If you have any questions concerning the material discussed in this client alert, please contact the members of our Medical Devices and Diagnostics practice.

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