Quarterly Medical Device Warning Letters Update: July – September 2026

ALERT | NOVEMBER 16, 2026

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 third quarter of 2026 (July through September).[1]

As of November 16, 2026, FDA posted nine warning letters that were issued in the third quarter of 2026 alleging violations of the Food, Drug, and Cosmetic Act (FDCA) related to medical devices.[2] Key trends and notable allegations in warning letters this quarter include:

1. **Most Commonly Cited Violations**: Eight of nine letters alleged violations of quality system requirements, with five letters alleging violations based on inspections conducted under the Quality Management System Regulation (QMSR) and three letters alleging violations based on inspections conducted under the prior Quality System Regulation (QSR). Design controls were a key focus, with four of five QMSR letters alleging violations of Clause 7.3 of ISO 13485 (Design and development) and all three of the QSR letters alleging violations of 21 CFR 820.30 (Design control). Supplier controls were also a consistent focus, with all five QMSR letters alleging violations of Clause 7.4 of ISO 13485 (Purchasing) and one of three QSR letters alleging violations of 21 CFR 820.50 (Purchasing controls). The letters also reflected a sustained focus on risk management under the QMSR, with four of five letters alleging violations of Clause 7.1 of ISO 13485 (Planning of product realization).

2. **Software Modifications Requiring Premarket Notification:** In a warning letter to **O.N. Diagnostics, LLC**, FDA alleged, based on a review of the software version control log and release notes, that the company significantly modified its VirtuOst Vertebral Fracture Assessment (VFA) device by introducing a new machine learning algorithm for vertebral landmarking. FDA stated that the new model, that was "trained on different data," required validation because the "new feature fundamentally changes how the device performs, fails, and affects patients in ways that go beyond what was originally cleared." The warning letter alleged that the need for validation of the algorithm triggered a 510(k) requirement: "Inadequate validation of this new feature may lead to a device that is unable to perform clinically as expected, which may result in patient harm such as missed or inadequate diagnosis, absence or delay of results, leading to missing, inaccurate, or delayed patient assessment. It can also lead to incorrect patient management due to misinterpretation of device output or overreliance on device output for radiological image interpretation. Thus, a new premarket notification is required."

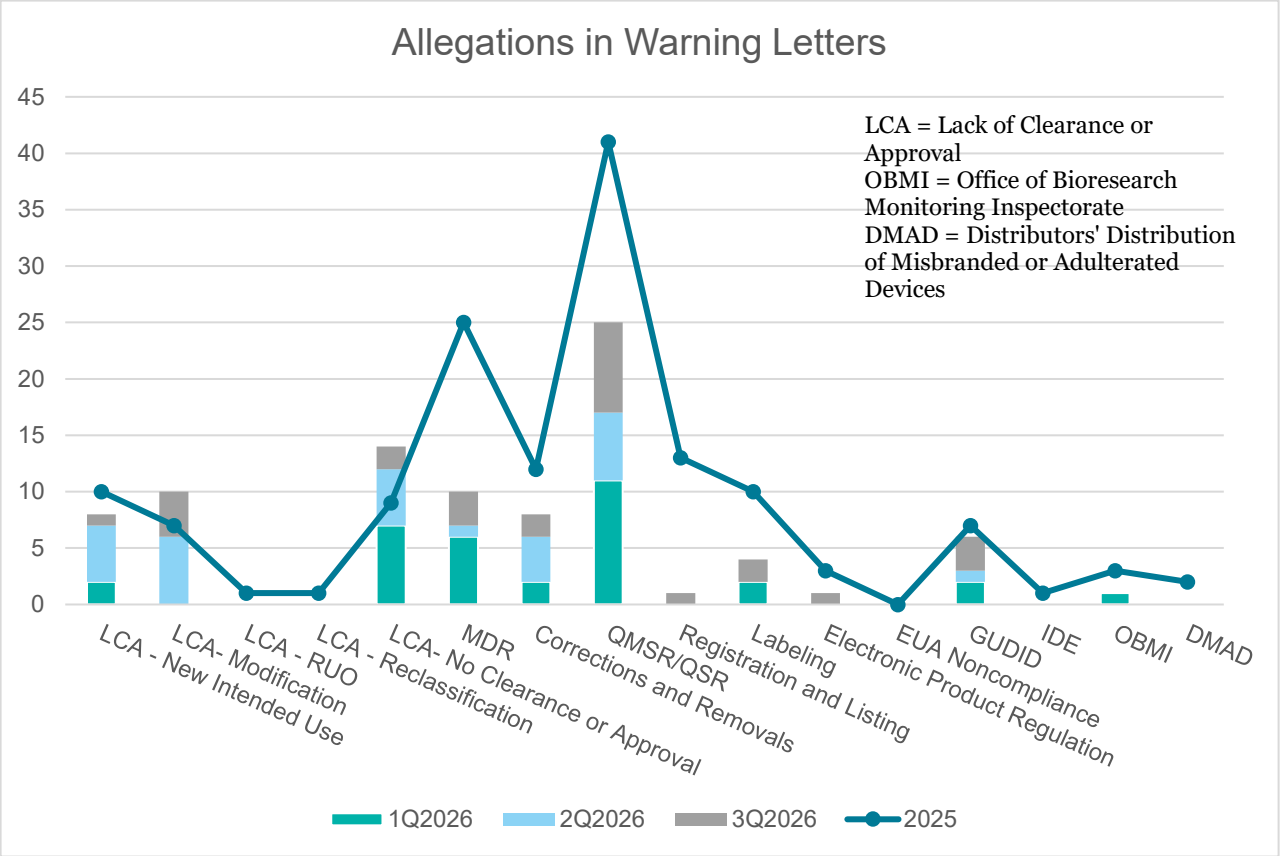
   The Agency also stated that a new 510(k) was required for two technology migrations that "each independently raise significant regulatory concerns." FDA stated that the device's migration "from a desktop application to a web-based architecture … introduces network-exposed attack surfaces, authentication vulnerabilities, and other cybersecurity risks inherent to internet-accessible

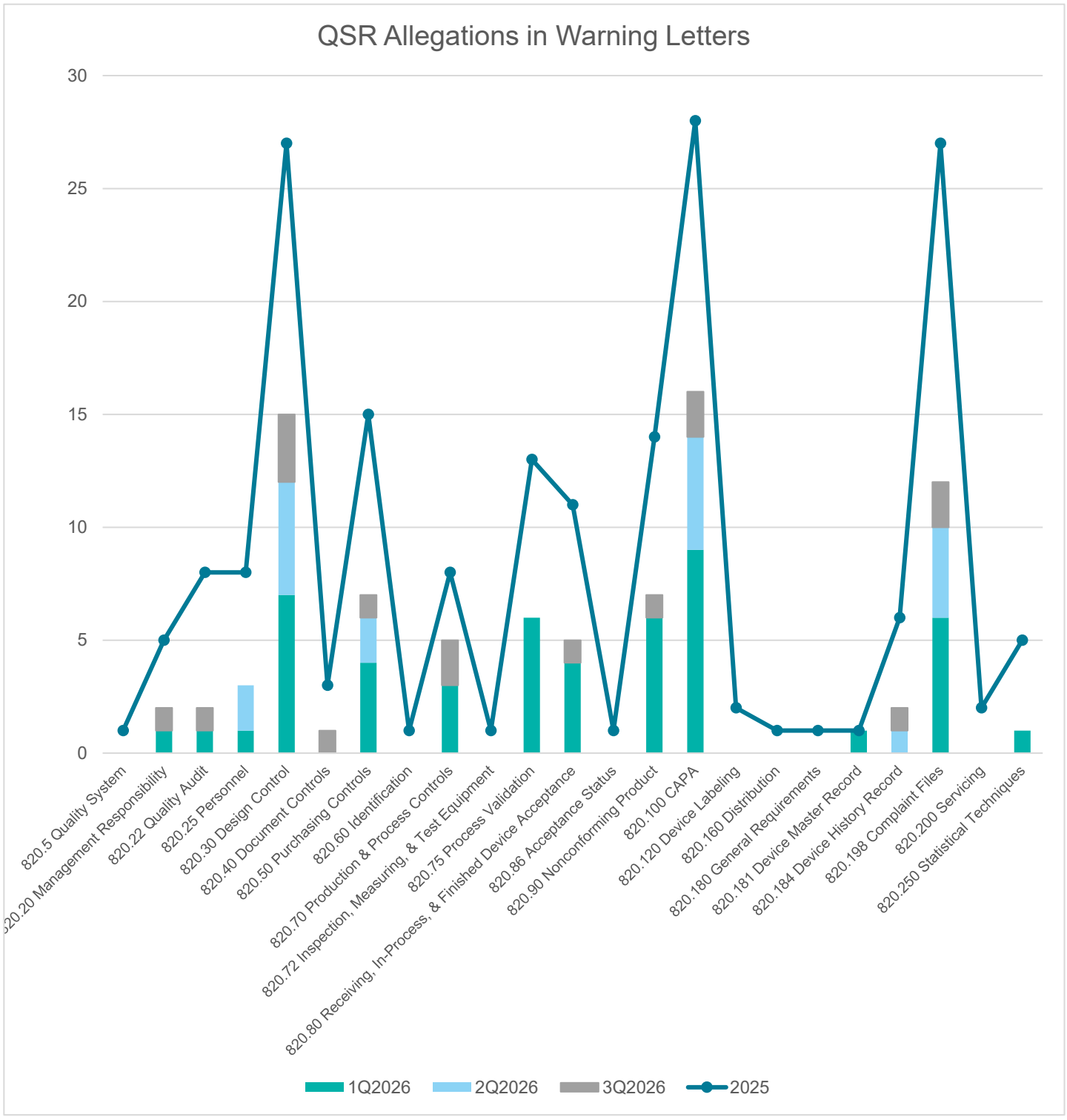
[1] This alert summarizes some of the allegations contained in FDA's letters. It does not contain any analyses, opinions, characterizations, or conclusions by Covington & Burling LLP. The information presented herein does not necessarily reflect the views of Covington & Burling LLP or any of its clients.

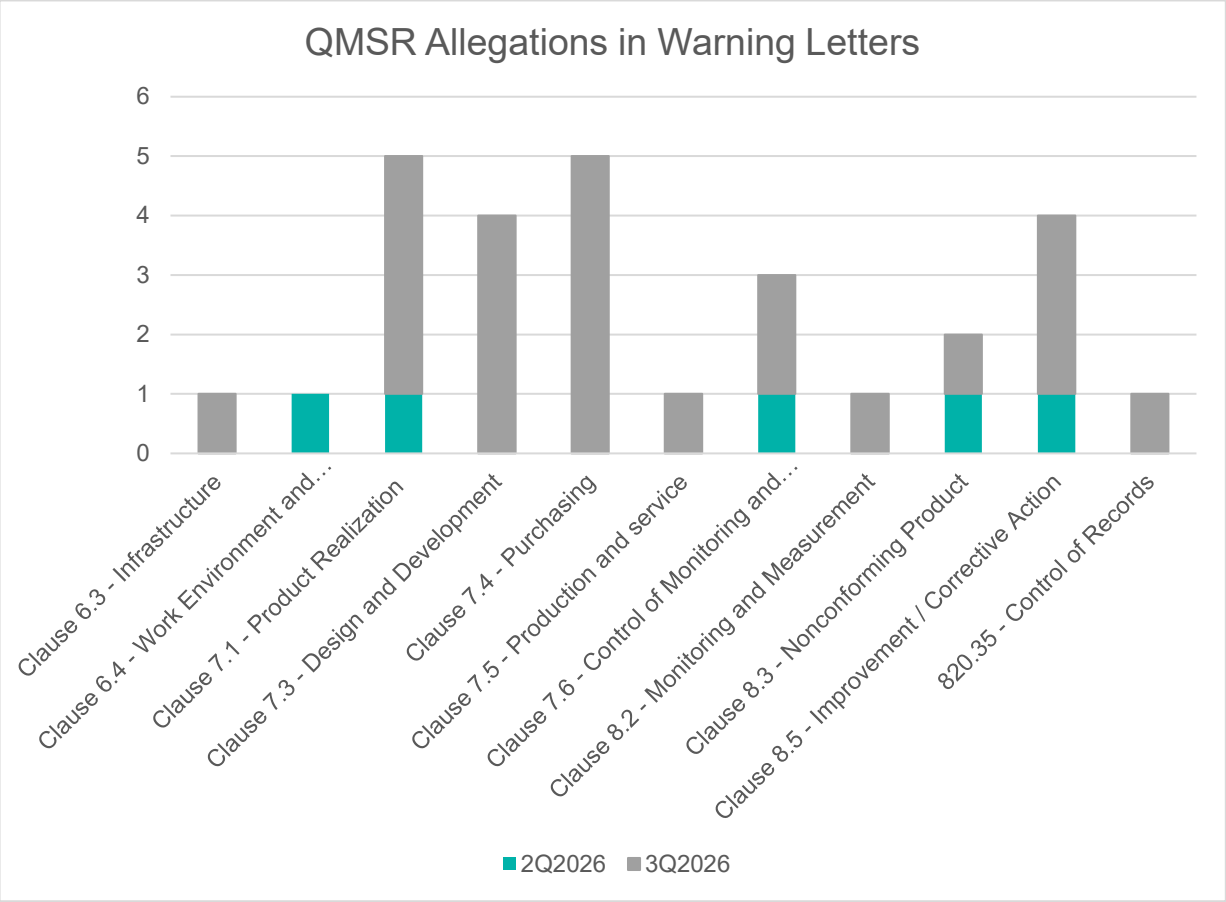
[2] These warning letters include only those that were publicly posted by FDA as of the date listed, including: **CMS #726564** (July 7, 2026), **CMS #734643** (July 21, 2026), **CMS #732874** (July 24, 2026), **CMS #727918** (Aug. 19, 2026), **CMS #733015** (Aug. 21, 2026), **CMS #729267** (Aug. 25, 2026), **CMS #727888** (Aug. 26, 2026), **CMS #730301** (Sept. 1, 2026), and **CMS #738562** (Sept. 22, 2026). Late posted letters will be addressed in a future client alert.

platforms." A second migration of the "technology platform" "necessitates comprehensive re-verification and re-validation of the entire software codebase." The letter serves as a reminder that all changes, even when not specifically intended to change a device software function, must be evaluated for their impact on the safety or effectiveness of that device software function, including the potential for introduction of new software and cybersecurity risks.

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
820.20 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
1Q2026
2Q2026
3Q2026
2025



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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