Quarterly Medical Device Warning Letters Update: April – June 2026

ALERT | SEPTEMBER 8, 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 second quarter of 2026 (April through June).[1]

As of September 8, 2026, FDA posted twelve warning letters that were issued in the second 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**: Lack of clearance or approval was the most commonly alleged violation, appearing in eleven of the twelve warning letters. Specifically, six letters involved modifications that FDA alleged required a new 510(k), five involved marketing devices for new intended uses without the required clearance or approval, and five involved devices FDA alleged were marketed without any clearance or approval.

   Five letters allege QSR violations, with design control (21 CFR 820.30) violations and corrective and preventive action (CAPA) violations (21 CFR 820.100) each cited in five letters. Complaint files (21 CFR 820.198) were cited in four letters.

   As we noted last quarter, FDA continues to issue warning letters based on inspections conducted under the QSR while acknowledging that the Quality Management System Regulation (QMSR) is now in effect. In these letters, FDA cites QSR-based observations but expects companies to address those observations through QMSR-corrective actions. As discussed further below, however, FDA has now begun issuing letters citing alleged violations of the QMSR.

2. **First QMSR Warning Letter**: The **Linemaster Switch Corporation** warning letter is the first published warning letter to allege violations of the QMSR. FDA alleged that Linemaster's foot-pedal accessories are adulterated because the company failed to comply with QMSR requirements concerning rework, risk management, corrective action, work environment, and monitoring and measurement equipment. The letter reflects an increased focus on risk management, and FDA alleged the company's risk management procedure "does not define how risk management activities are performed and documented, who is responsible for conducting and approving risk management activities, when risk management documentation must be updated, and how post-market feedback data (including complaints, adverse events, and recalls) is incorporated into risk management." As additional QMSR-based warning letters are issued, this alert will track alleged violations and identify trends, much as it did previously with QSR-based warning letters.

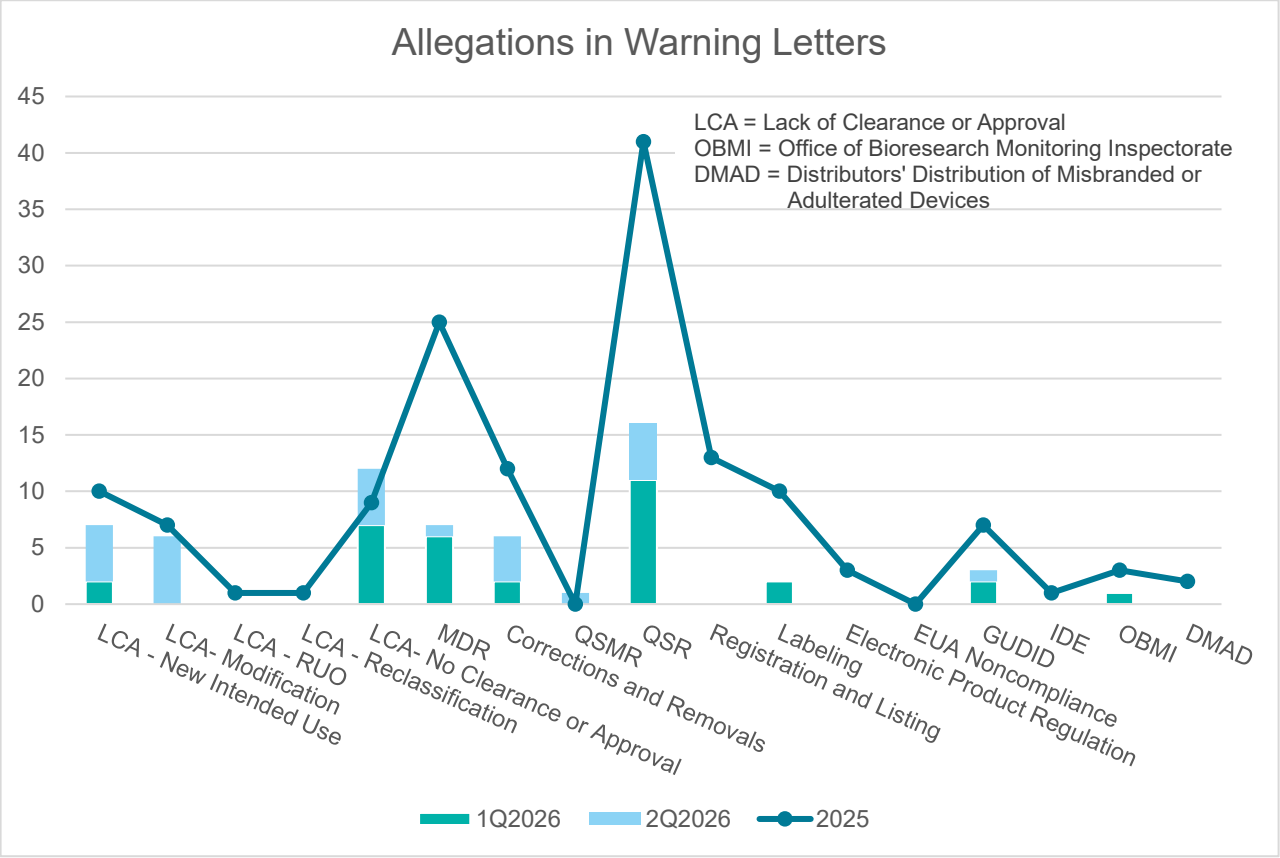
3. **One Inspection, Two Warning Letters**: FDA issued separate warning letters to **BMC Medical Co., Ltd.** (BMC) and **3B Medical, Inc. dba React Health, Inc.** (React), which occupy different manufacturing

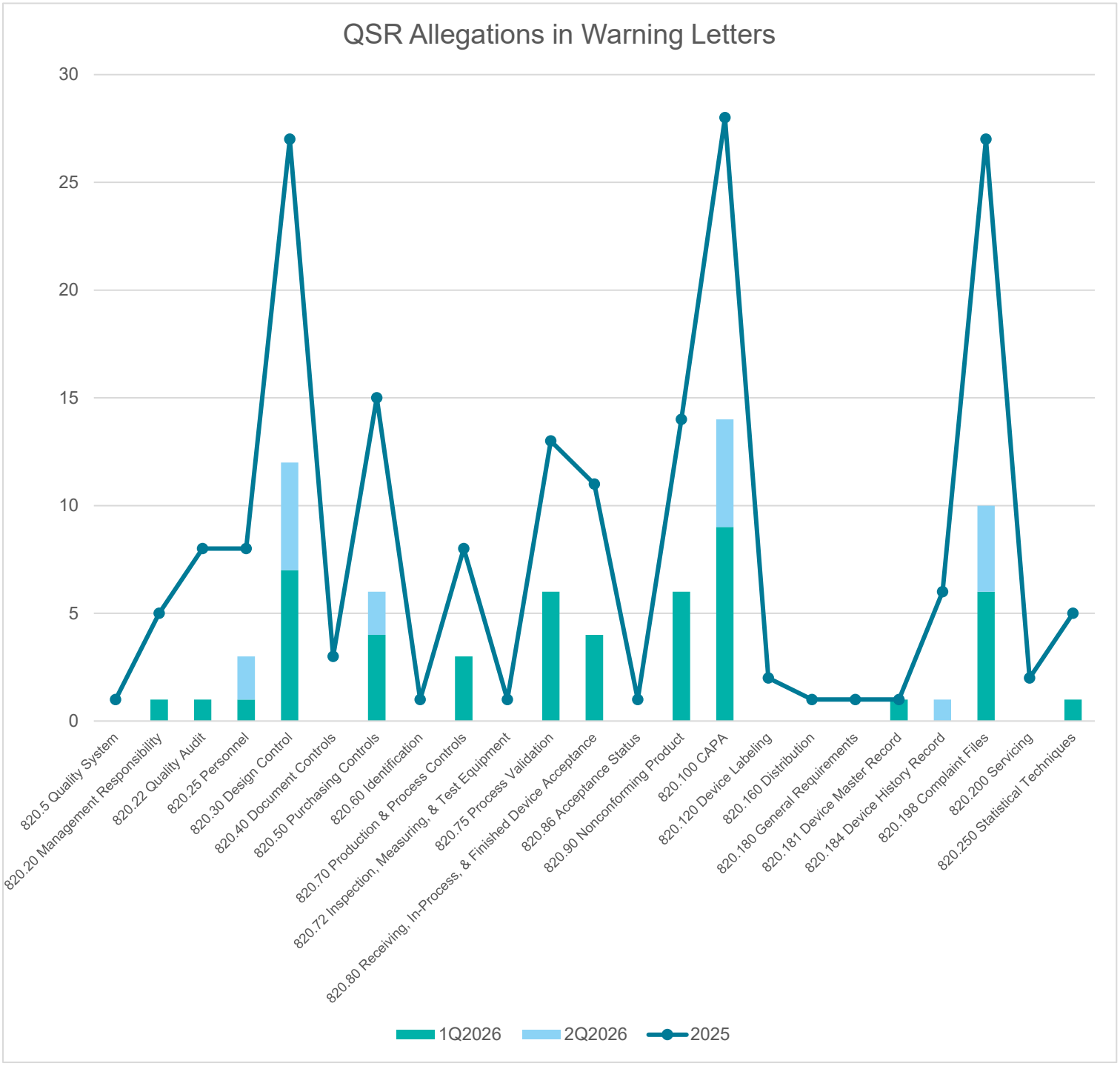
[1] This alert summarizes some of the allegations contained in FDA's letters. It does not contain any analyses, opinions, characterizations, or conclusions by Covington & Burling LLP. The information presented herein does not necessarily reflect the views of Covington & Burling LLP or any of its clients.

[2] These warning letters include only those that were publicly posted by FDA as of the date listed, including: CMS #724245 (Apr. 15, 2026), CMS #716831 (Apr. 22, 2026), CMS #711320 (Apr. 30, 2026), CMS #723950 (May 19, 2026), CMS #725108 (May 20, 2026), CMS #725759 (May 20, 2026), CMS #725870 (May 22, 2026), CMS #730215 (May 27, 2026), CMS #725861 (June 3, 2026), CMS #728184 (June 4, 2026), CMS #727803 (June 12, 2026), and CMS #718306 (June 15, 2026). Late posted letters will be addressed in a future client alert.

roles (specification developer and importer, respectively) in the supply chain for the same Auto-Adjusting Positive Airway Pressure (APAP) devices. While it is not uncommon for FDA to issue warning letters to multiple entities involved in the manufacture and distribution of the same device, in this case, both warning letters were predicated on an inspection of only a single manufacturer, React, and it does not appear that FDA conducted a separate inspection of BMC. Instead, the warning letter to BMC relies on information obtained during FDA's inspection of React to allege that BMC significantly modified the devices without obtaining new 510(k) clearances. The warning letters illustrate that FDA may rely on information obtained during the inspection of one manufacturer to support enforcement actions against another manufacturer involved with the same device.

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
2025

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