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# Quarterly Medical Device Warning Letters Update: April – June 2025

August 19, 2025

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 second quarter of 2025 (April through June).[1]

As of August 19, 2025, FDA posted twelve warning letters that were issued in the second quarter of 2025 alleging violations of the Food, Drug, and Cosmetic Act (FDCA) related to medical devices.[2] Two letters issued in the first quarter were posted, as well. Key trends and notable allegations in warning letters this quarter include:

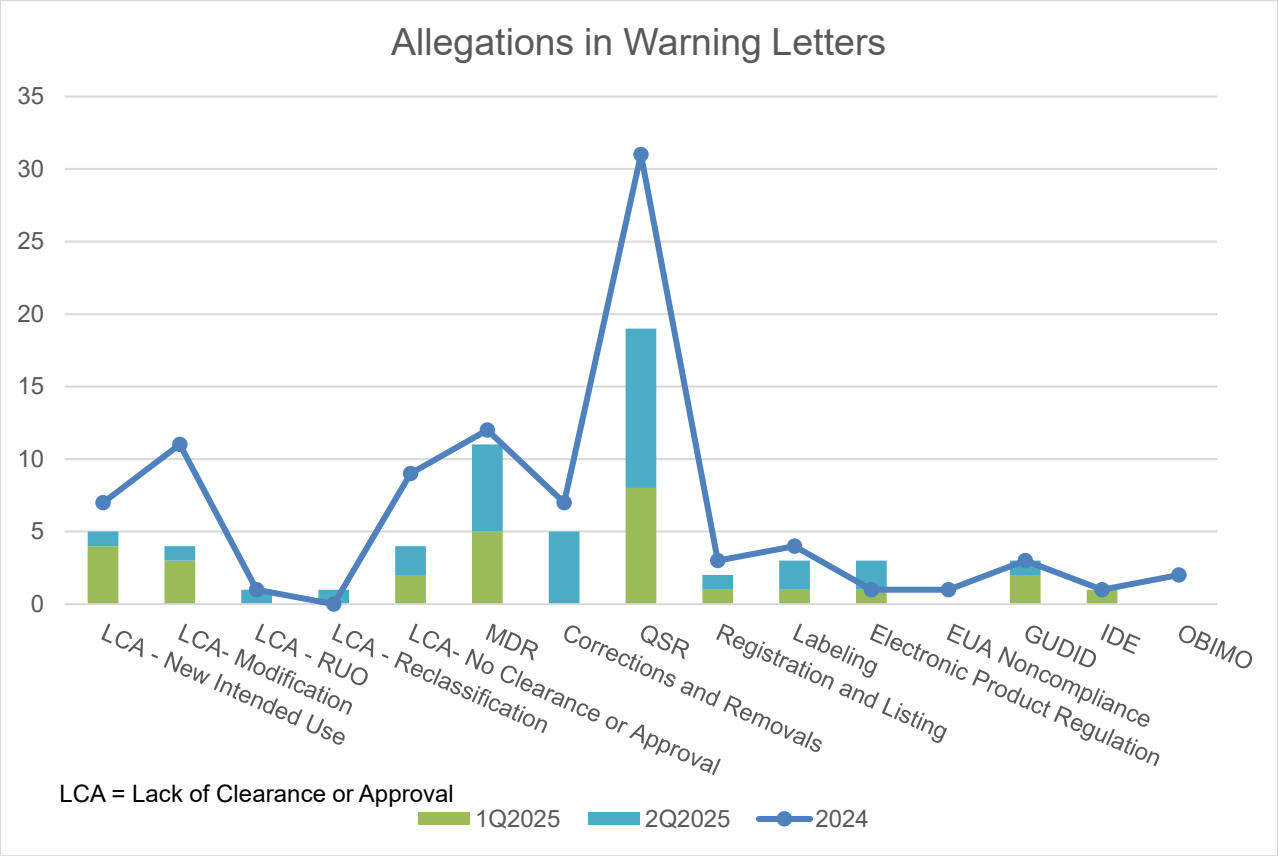
1. **Most Commonly Cited Violations**: Twelve of the fourteen letters allege violations of the quality system regulations (QSR), continuing the trend of alleged QSR violations as the most commonly cited allegations. The most commonly alleged QSR violations related to corrective and preventive action (CAPA) (21 CFR 820.100), design controls (21 CFR 820.30), and complaint files (21 CFR 820.198), cited in eight letters each. Additionally, alleged violations of requirements for nonconforming products (21 CFR 820.90) were cited in five letters, and alleged violations of requirements for purchasing controls (21 CFR 820.50) and process validation (21 CFR 820.75) were alleged in four letters each.
2. **Dental Device Manufacturer Not a Dental Laboratory**: In a warning letter to Reset Technology Corporation, FDA alleges the firm manufactures partial denture devices and impression kits and fails to comply with several requirements—including among others, registration and listing—rendering such devices adulterated and misbranded. FDA states the company took the position that it is exempt from registration and listing under 21 CFR 807.65(i) because it is a dental laboratory that "manufactures patient specific restorative devices (removable partial dentures) based upon a prescription from a licensed dentist" and "use[s] FDA cleared materials ... to manufacture each patient specific device and do[es] not commercially distribute these devices." FDA rejects this

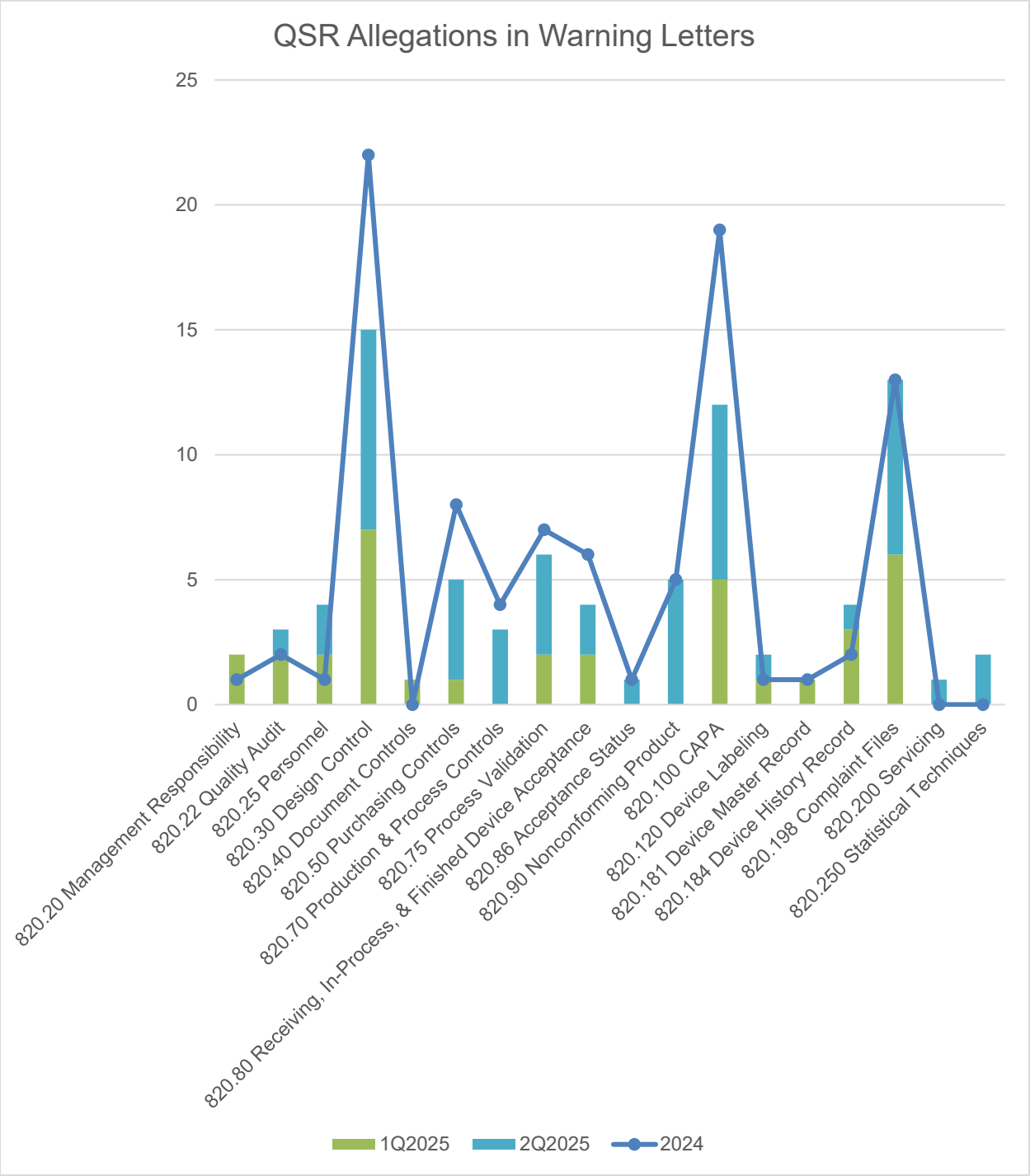
[1] This alert summarizes some of the allegations contained in FDA's letters. It does not contain any analyses, opinions, characterizations, or conclusions by Covington & Burling LLP. The information presented herein does not necessarily reflect the views of Covington & Burling LLP or any of its clients.
[2] These warning letters include only those that were publicly posted by FDA as of the date listed, including: CMS #697777 (Mar. 24, 2025), CMS #700918 (Mar. 31, 2025), CMS #702535 (Apr. 4, 2025), CMS #702414 (Apr. 9, 2025), CMS #707156 (May 5, 2025), CMS #705464 (May 6, 2025), CMS #707614 (May 8, 2025), CMS #705489 (May 9, 2025), CMS #704563 (May 9, 2025), CMS #704823 (May 21, 2025), CMS #706921 (June 3, 2025), CMS #704828 (June 9, 2025), CMS #709010 (June 13, 2025), and CMS #707997 (June 27, 2025). Late posted letters will be addressed in a future client alert.

argument, stating that the company "is not providing a service through the use of previously manufactured devices. Rather, [the] firm manufactures and distributes partial denture devices using devices that lack required approval/clearance and manufactures and distributes impression kits comprised of devices that lack required approval/clearance."

3. **Research Use Only (RUO) Products:** In a late-posted Q1 warning letter to DRG Instruments GmbH (March 31, 2025), FDA alleges that the company's Salivary Cortisol ELISA RUO product appears intended for clinical diagnostic use, notwithstanding the product's labeling for research use only. FDA points to statements on DRG's website, labels reviewed at inspection, and customer records that indicate clinical diagnostic intended use. For example, the warning letter describes:
    - instructions for use distributed with the product that contain a specimen collection and preparation section, as well as a section on quality control. The Agency asserts that "[t]his type of language is typically included for IVDs that are intended for clinical diagnostic use, as this type of information is consistent with the prospective testing of patients and is not the type of information that is necessary for an assay in the laboratory research phase of development."
    - customer records that show the firm sold and shipped its RUO-labeled product to multiple companies in the business of performing clinical analysis, where there was no indication that these companies also conduct research.
    - absence of a certification letter from one of the company's customers, when the firm had otherwise provided copies of such letters as evidence that customers knew the devices were intended for research purposes only.
4. **Failure to Submit PMA for Reclassified Device**: FDA alleges Insightra Medical, Inc. failed to submit a premarket approval application (PMA) or product development protocol (PDP) for its previously cleared intra-aortic balloon and control system after such devices were reclassified from class II to class III when indicated for septic shock or pulsatile flow generation. While Insightra's devices had been cleared with the up-classified indications, FDA alleges the company did not submit a PMA or PDP following reclassification, nor did it submit an add-to-file to its previously cleared 510(k) to remove such indications, and the company continued to include septic shock and pulsatile flow generation as indications in its operations manual. FDA states it previously sent the company a letter clarifying expectations for compliance with the reclassification order.
5. **Continuation of Data Quality Issues**: In a prior alert, we described two warning letters that FDA had issued to third-party non-clinical testing laboratories in China, in which the Agency alleged violations of Good Laboratory Practice (GLP) requirements. This quarter, FDA issued two General Correspondence Letters to these companies alleging that data was falsified or found to be unreliable, and stating the Agency will reject data generated in those facilities for use in premarket device submissions.

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






If you have any questions concerning the material discussed in this client alert, please contact the following members of our Medical Devices and Diagnostics practice: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