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Quarterly Medical Device Warning Letters Update: January – March 2025

May 9, 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 first quarter of 2025 (January through March).[1]

As of May 9, 2025, FDA posted eight warning letters that were issued in the first quarter of 2025 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. **QSR Allegations Continue to Top the Charts**: Seven of the eight letters allege violations of the quality system regulations (QSR), continuing the trend of alleged QSR violations being the most commonly cited allegations. All seven letters alleged violations related to design controls under 21 CFR 820.30, and four of these letters specifically alleged violations related to design changes under 21 CFR 820.30(i). Additionally, five letters alleged violations related to complaint files under 21 CFR 820.198, and four letters alleged violations related to corrective and preventive action (CAPA) under 21 CFR 820.100. Design controls, complaint files, and CAPAs also were the most commonly alleged QSR violations in 2024.
2. **Device Changes Continue to Trigger Warning Letters**: FDA issued six warning letters this quarter alleging that changes to devices required new 510(k)s: four regarding the device's intended use, and two regarding technology modifications. In a few of these letters, FDA expressly discussed information from the original 510(k) submissions—information beyond the publicly available indication statement or design change information collected during an inspection—to support that the device had been changed from the version that was cleared.

   For example, in a letter to Q'Apel Medical, Inc., FDA alleges the company's 072 Aspiration System was modified in a way that requires 510(k) clearance and compares promotional and inspection data to drawings in the premarket notification and a

[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.

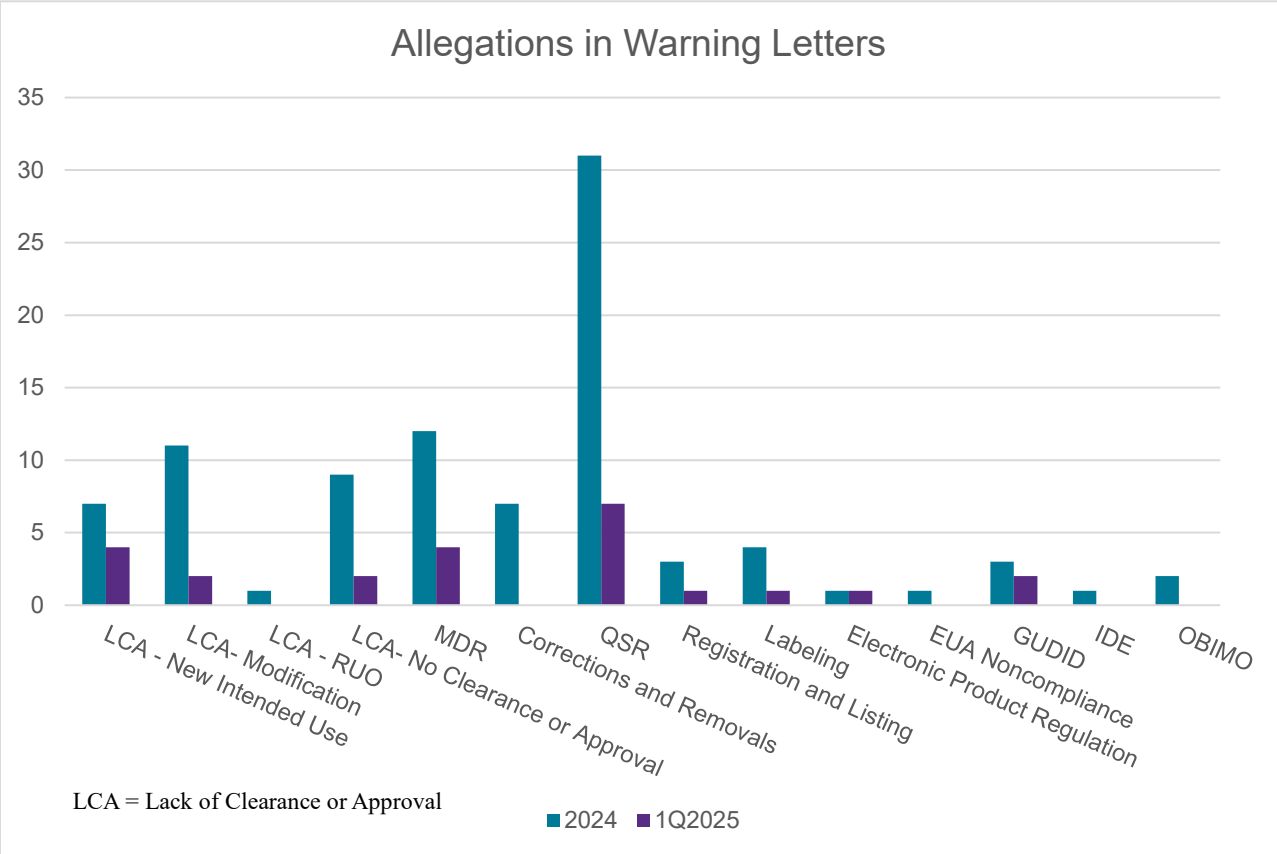
[2] These warning letters include only those that were publicly posted by FDA as of the date listed, including: CMS #687984 (Jan. 21, 2025), CMS #699244 (Feb. 5, 2025), CMS #699218 (Feb. 10, 2025), CMS #692368 (Feb. 21, 2025), CMS #698114 (Feb. 21, 2025), CMS #700835 (Mar. 4, 2025), CMS #676429 (Mar. 12, 2025), and CMS #702493 (Mar. 21, 2025). Late posted letters will be addressed in a future client alert.

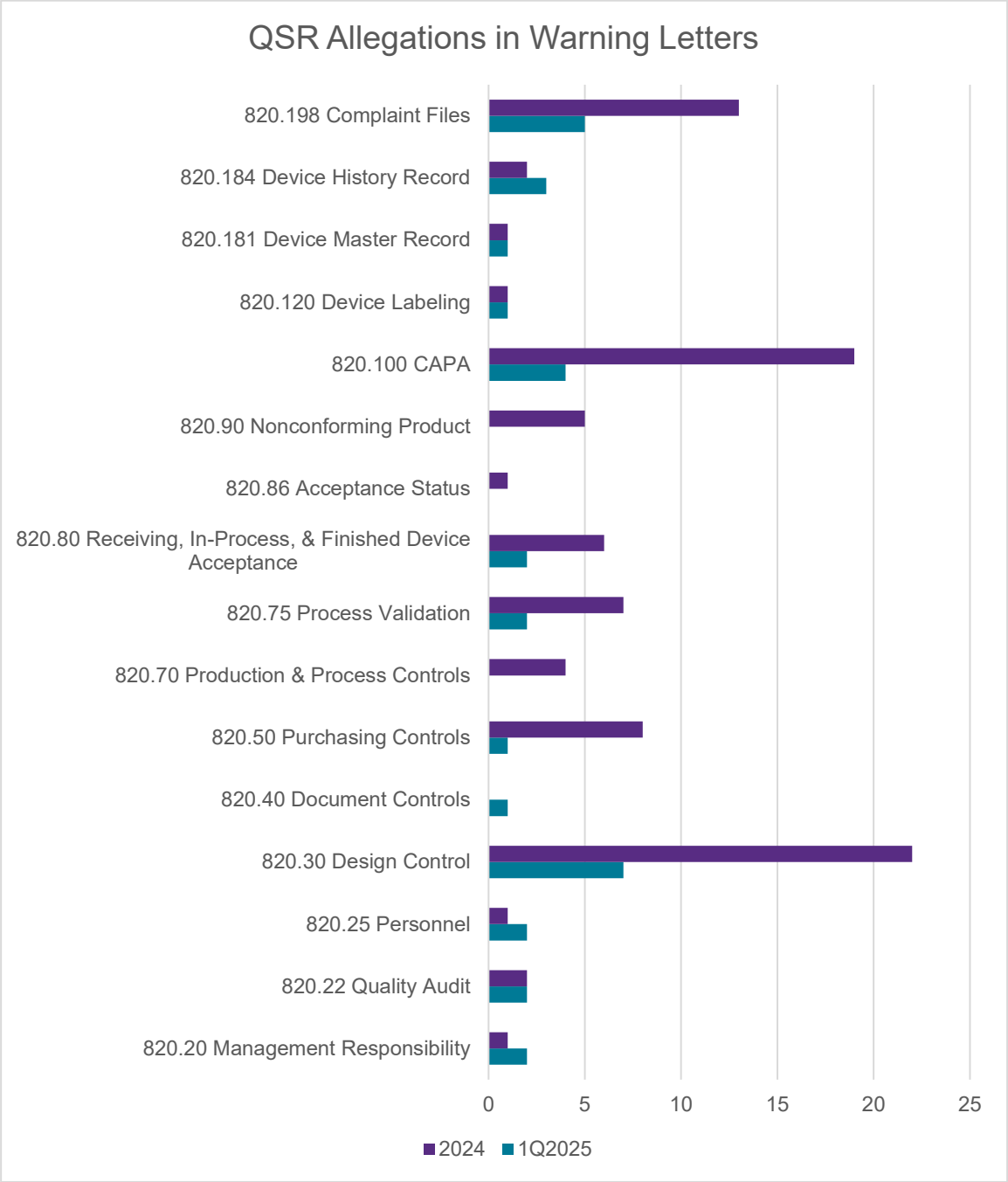
quotation from the company's response to an earlier Refuse-to-Accept (RTA) notification. Whereas the company marketed the marketed device has a nitinol tip that allows for expansion in diameter and compression in length, the drawings and images in the premarket notification did not show compression of the nitinol tip, and the RTA response expressly stated that the tip "does not have an active mechanism of action and is not self-expanding." FDA's warning letter states that the information it gathered during inspection "raises concerns that the information provided to FDA for review in [the premarket notification] did not accurately disclose the technological characteristics" of the device.

Additionally, in a letter to Rex Implants Inc., FDA alleges that the company's Piezoimplant System has a new intended use that requires 510(k) clearance and compares the instructions for use (IFU) of the marketed device to the IFU submitted in the premarket notification. Whereas the current IFU says the surgeon can place the implant deeper if there is implant mobility upon placement, the IFU for the cleared device says the implant should be removed in these circumstances.

3. **Manufacturers Told to Expect Follow-Up Inspections**: In three letters, FDA expressly states that it intends to conduct follow-up inspections to verify the effectiveness of corrective actions. FDA had not made such statement express in any of its posted warning letters that were issued in 2024.

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:

Scott Danzis	+1 202 662 5209	sdanzis@cov.com
Amy Leiser	+1 415 591 7069	aleiser@cov.com
Natalie Maas	+1 415 591 6022	nmaas@cov.com