U.S. FOOD & DRUG ADMINISTRATION
Office of Regulatory Affairs

U.S. Food and Drug Administration
Office of Regulatory Affairs
Office of Medical Device and Radiological Health Operations (OMDRHO) Division 2 – Central
555 Winderley Pl # 200
Maitland, FL 32751
Telephone: (407) 475-4700
www.fda.gov

Communication Resources following an FDA Inspection

About OMRHO Office of Medical Device and Radiological Health Operations

OMDRHO has 3 divisions. Your firm is located within Division 2 boundaries. Division 2 covers the states of: AL, FL, GA, IA, IL, KS, LA, MN, MO, MS, NC, ND, NE, SC, SD, TN, WI, Puerto Rico, and the US Virgin Islands.

FDA-483 Responses

Please E-mail your inspection-related correspondence to ORADevices2FirmResponse@fda.hhs.gov . Include your company's name FEI number found on the form FDA-483 in the subject of the email, and on the cover letter or attachments. We prefer e-mail correspondence due to efficiency, fiscal responsibility, expedited service to stakeholders and environmental awareness. Be sure that any attachments are labeled and/or identified for ease of review and submitted as **a single pdf file**. If a single pdf file exceeds the 100MB size limit, submit multiple pdf files, with bookmarks, as appropriate. Do not provide multiple folders that contain individual files as this will delay the processing of your response. The Division will acknowledge receipt of your e-mail. There is no need to provide a back-up hard copy of correspondence sent via email.

Hard copy, thumb drive, and compact disc (cd) responses are discouraged, but if that is the only way you can send a response, please use the address listed below.

U.S. Food and Drug Administration
Office of Medical Device and Radiological Health Operations Division 2 – Central ATTN:
OMDRHO Program Division Director
555 Winderley Place, Suite 200
Maitland, FL 32751

OMDRHO Division 2 – Central Contacts:

Blake Bevill, Program Division Director (PDD) manages all inspections and compliance activities.	Blake.Bevill@fda.hhs.gov (407) 475-4734
James Hildreth, Director of Investigations Branch (DIB) manages all inspectional activities.	James.Hildreth@fda.hhs.gov (404) 669-4555
Melissa Michurski, Director of Compliance Branch (DCB) manages FDA-483 responses and post-inspection compliance activities.	Melissa.Michurski@fda.hhs.gov (612) 758-7185
Recall Coordinators	Meredith Andress (334) 273-4788 ext. 106 Marie Fink (504) 846-6109

Medical device recalls: Submit recall (21 CFR 806) information to oradevices2recalls@fda.hhs.gov

For general information on recalls, corrections and removals, visit:
www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals/

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Final Rule: Revised FDA regulation effective in 2026

On February 2, 2026, the *Quality Management System Regulation* (QMSR) will go into effect. On the effective date, FDA device inspections will review a manufacturer's compliance with this revised regulation. Links to the final rule and the Frequently Asked Questions can be found on OMDRHO's webpage www.fda.gov/ORADevices

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> On 02/02/2024 the agency published Quality Management System Regulation: Final Rule. Read the rule. For more information read the Frequently Asked Questions FDA.

If you have questions about the QMSR, contact the Center for Devices and Radiological Health's (CDRH) Division of Industry and Consumer Education (DICE).

E-mail: DICE@fda.hhs.gov
Phone: 1 (800) 638-2041 or (301) 796-7100
https://www.fda.gov/DICE

Additional useful links:

- For general information about **OMDRHO inspections**, including your inspection report, visit: www.fda.gov/ORADevices
- For general information about **device registration and listing**, visit: https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing
- For general information on **mandatory reporting requirements**, visit: https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities