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

New FDA Contact Information

Your firm now has new FDA contacts to correspond with regarding your medical device inspections. Your inspections are now managed by the Office of Regulatory Affairs' Office of Medical Device and Radiological Health Operations (OMDRHO) Division 2 – Central.

What is the Office of Medical Device and Radiological Health Operations (OMDRHO) Division 2 – Central?

This division solely works with medical devices. It 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.

How do I submit my FDA-483 Response following my inspection?

E-mail your inspection-related correspondence to the email address listed below. Please include your company's FEI number, if known, in the subject of the email, and on the cover letter or documentation. Hard copy responses are discouraged, but if that is the only way you can send a response, please use the address listed below. Thumb drive or compact disc (cd) may be sent to the address below.

We prefer e-mail correspondence due to efficiency, fiscal responsibility, expedited service to stakeholders and environmental awareness. The Division will acknowledge receipt of your e-mail (size limit 100 megabytes) to ORADevices2FirmResponse@fda.hhs.gov.

Please be sure that any attachments are readily labeled and/or identified for ease of review to include the FEI number. Documentation should be submitted as **a single pdf file**, with bookmarks to easily identify table of contents, memos, attachments, etc. If a single pdf file exceeds the 100MB size limit, please submit multiple pdf files, with bookmarks, as appropriate. Please do not provide multiple folders that contain individual files as this will delay the processing of your response. There is no need to provide a back-up hard copy of any correspondence sent via email or provided in thumb drive or cd format.

E-mail FDA-483 responses to ORADevices2FirmResponse@fda.hhs.gov

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

Who do I contact about my medical device recall?

Contact the e-mail address below and a recall coordinator will contact you.

oradevices2recalls@fda.hhs.gov
Meredith Andress (334) 273-4788 ext 106
Marie Fink (504) 846-6109
Lisa Warner (407) 475-4735

8/2021

What other contact information do I need to know?

After the inspection, a copy of the establishment inspection report (EIR) will be issued to the most responsible person at the facility in accordance with Field Management Directive 145. In most cases, the EIR will be issued electronically via email from ORADEVICES2FMD@fda.hhs.gov. The EIR will come secured with a password issued in a separate email. If you have issues or concerns with your EIR, please reach out to this email address for resolution.

The Program Division Director (PDD), OMDRHO Division 2 – Central, manages all inspections and compliance activities. Blake Bevill is the PDD and can be reached by email at Blake.Bevill@fda.hhs.gov or phone at 407-475-4734.

The Director of Compliance Branch (DCB), OMDRHO Division 2 – Central, manages FDA-483 responses and post-inspection compliance activities. Melissa Michurski, DCB, can be reached by email at Melissa.Michurski@fda.hhs.gov or by phone at (612) 758-7185.

The Director of Investigations Branch (DIB), OMDRHO Division 2 – Central, manages all inspectional activities. The Acting DIB can be reached by email at oradevices2actingdib@fda.hhs.gov.

Why are you changing my FDA contacts?

In May 2017, as part of a broader agency initiative called program alignment, the U.S. Food and Drug Administration's (FDA) Office of Regulatory Affairs (ORA) implemented a program-based management structure that aligns staff by FDA-regulated product. This organizational approach replaces a management structure based on geographic regions. The changes within ORA are being made as part of the agency's Program Alignment strategy to modernize and strengthen the FDA's workforce and improve our public health response.

For more information on program alignment, visit:
https://www.fda.gov/aboutfda/centersoffices/officeofglobalregulatoryoperationsandpolicy/ora/ucm549087.htm

More Information

For general medical device regulatory questions, you may 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
www.fda.gov/DICE

- **For training videos and slides, visit:** www.fda.gov/Training/CDRHLearn
- **For general information about device registration and listing, visit:** www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/
- **For general information on recalls, corrections and removals, visit:** www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals/
- **For general information on mandatory reporting requirements, visit:** www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents