

Resolving disputes concerning FDA and medical devices

Mass Device

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Disagreements are inevitable in science, medicine – and even life. As part of a regulatory agency committed to public health, the FDA's medical devices center occasionally confronts scientific and policy disagreements among our staff and with the various stakeholders we strive to serve.

Disputes can occur at any stage of a particular interaction, from an initial inquiry or pre-submission review to a final regulatory decision on an application or submission.

As [Ombudsmen for FDA's medical devices center](#) [1], our office investigates complaints from outside the FDA and facilitates the resolution of disputes between FDA's medical devices center and the industry we regulate.

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<http://www.mdtmag.com/news/2013/07/resolving-disputes-concerning-fda-and-medical-devices>

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[1] <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHombudsman/default.htm>