Allegations of Regulatory Misconduct Form

OMB control number: 0910-0769
Approval Expiration Date: 8/31/17

This form is to report an allegation of regulatory misconduct, a claim that a medical device manufacturer or individuals marketing medical devices may be doing so in a manner that violates the law. Submitting an allegation is voluntary, and the form does not have to be complete in order for the allegation to be reviewed.

Please include as much of the following information as possible to help the FDA assess the allegation you are reporting:

Name of the company for which you are submitting an allegation:

Company Name

Telephone number of the company:

Company Phone

Address of the company:

Company Street Address

*** Name and model (if applicable) of the Medical Device(s) in question:**

Device Name

Lot numbers / serial numbers / part numbers:

Lot, Serial, or Part Numbers

*** Detailed description of the allegation with any available supporting documentation:**

Description

Your Name:

Your Name

Your Email:

Your Email

Submit Clear Form

Please email any document attachments to **OCMedicalDeviceCo@fda.hhs.gov (mailto:OCMedicalDeviceCo@fda.hhs.gov?subject=Allegation%20of%20Regulatory%20Misconduct%20File%20Attachments)**. Please send attachments from your email address used above.

More in Reporting Allegations of Regulatory Misconduct (/MedicalDevices/Safety/ReportingAllegationsofRegulatoryMisconduct/default.htm)

- **Allegations of Regulatory Misconduct Form (/MedicalDevices/Safety/ReportingAllegationsofRegulatoryMisconduct/ucm526129.htm)**