How to Report a Medical Device Problem

Medical device reports are submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters (health care professionals, patients, caregivers and consumers).

The Medical Device Reporting (MDR) regulation (21 CFR Part 803) contains mandatory requirements for manufacturers, importers, and device user facilities to report certain device-related adverse events and product problems to the FDA. The regulation specifies that reports be filed on the FDA's Medwatch Form 3500A or an electronic equivalent. The FDA requires manufacturers and importers to submit MDRs to the FDA in an electronic format that the FDA can process review, and archive.

MedWatch Online Voluntary Reporting

Health professionals, consumers and patients can voluntarily report observed or suspected adverse events for human medical products to FDA. Voluntary reporting can help FDA identify unknown risk for approved medical products. Reporting can be done online by downloading, completing and then submitting FDA Form 3500 (Health Professional) or 3500B (Consumer/Patient) to "Med/Watch: The FDA Safety Information and Adverse Event Reporting Program".



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Ronald Evens

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