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.

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Fda Abbreviated Final Report Medical Device

Gordon Harnack

Fda Abbreviated Final Report Medical Device:

Unveiling the Magic of Words: A Review of "Fda Abbreviated Final Report Medical Device"

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