Resources for You (Medical Devices)
- Industry (Medical Devices)
- Letters to Industry
- CDRH Outreach Emails

FDA Announces Improvements To The Medical Device Recalls Database

Today, the Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH) is pleased to announce improvements to several public databases that will increase access to safety information on marketed medical devices. The improvements include adding new fields to the Medical Device Recalls database and providing links to the recall database from FDA's 510(k)Premarket Notification and Premarket Approval (PMA) databases.

Specifically:

- The 510(k) and PMA databases will have a CDRH Recalls hyperlink at the bottom of each record if there are recalls associated with that medical device.
- The recalls database has been expanded to include recall status (whether or not the recall has been terminated), product classification (product code), premarket submission numbers associated with the recall (510(k)s and PMAs only), and the root cause of the recall as determined by the FDA. Also, the previously available field "Reason for Recall" has been renamed "Manufacturer Reason for Recall" to better clarify the source of the information.
- In addition to the new and renamed fields, two new links are available at the bottom of recall records. The first will search the Total Product Lifecycle (TPLC) database for additional information regarding other devices with the same product code as the recalled device. The other will search the premarket databases for other premarket submissions of this type of product from the same applicant. This will provide information about submissions cleared or approved after the recall.

If you have questions about the database improvements, please contact the Division of Small Manufacturers, International, and Consumer Assistance (DSMICA) for assistance. DSMICA may be reached by phone at (800)638-2041 or (301)796-7100 to by email at industry.devices@fda.hhs.gov.

Food and Drug Administration
Center for Devices and Radiological Health

Page Last Updated: 12/13/2013
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