MEDICAL DEVICE RECALL

In the last 15 years, the most common causes of medical product recalls were due to:

- Device software malfunction
- Defective design
- Nonconforming components or materials

The most commonly recalled medical devices are: heart valves, pacemakers, prosthetic knees, hip devices and ventilators.

TAKE NOTE

Important fact about Medical Device Safety:

The FDA does not monitor healthcare professionals who use products for unapproved uses.

January - August 2016
24 medical products recalled.

6 MONTHS
24 RECALLS

Device Defects: 4 Levels Of Reporting Responsibility.

1 Manufacturers are legally required to notify the FDA of device defects with MDRs (Medical Device Reports) to be published as a notice to the public.

2 Importers are required to notify the FDA of a device defect in case of death or serious injury.

In case of malfunction they need to report to the manufacturer.

3 Device user facilities - hospitals, nursing homes, outpatient facilities, report to the FDA and the manufacturer in case of death.

They can voluntarily report a device malfunction using MedWatch form or MedWatcher mobile app.

4 Consumers, caregivers, patients and healthcare professionals are encouraged to submit a MedWatch form if they know of or experience a medical product problem.

SOURCES

http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhtransparency/ucm388442.pdf
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