Corrections and Removals
21 CFR Part 806

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WalkMed Infusion Issues Nationwide Recall of Triton Infusion Pump

FOR IMMEDIATE RELEASE – 11/5/2010
WalkMed Infusion LLC, Englewood, Colorado, is initiating a nationwide recall of a total of 2018 Triton Pole Mount Infusion Pumps. The pumps have been found to possibly have a problem with the pump door open alarm, which potentially could result in over infusion of medication.

Defibtech Announces a Voluntary Recall of DBP-2800 Battery Packs used in the Lifeline AED® and ReviveR AED

FOR IMMEDIATE RELEASE – 6/3/2010 - Guilford, CT – Defibtech, LLC, is initiating a voluntary recall of 5,418 DBP-2800 Battery Packs used in the Lifeline AED® and ReviveR AED. The AED may falsely detect an error condition during charging for a shock, then cancel charge and not provide therapy.

FDA Classifies Previous Field Action of Medtronic Surgical Device as Class I Recall

FOR IMMEDIATE RELEASE – 10/29/2010
Minneapolis - Medtronic, Inc. (NYSE: MDT) today announced the U.S. Food and Drug Administration (FDA) has classified the company’s previous action related to the Octopus® Nuvo Tissue Stabilizer as a Class I recall.
Objectives

• Review applicable sections of 21 CFR Part 7 and 21 CFR 806
• Review Correction and Removal definitions
• Understand FDA’s responsibilities regarding recalls
• Discuss inspectional activities
21 CFR Part 7: Recalls

**Recall** means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure.

- Usually conducted as a voluntary action
- An alternative to an FDA-initiated legal action
21 CFR Part 7: Recalls

**Correction** means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location

- **Removal** is not defined in Part 7
Recall does not include:

- **Market withdrawal** --- removal or correction of a distributed product which involves a minor violation or no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.

- **Stock recovery** --- removal or correction of a product that has not been marketed or that has not left the direct control of the firm, i.e., the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use.
Summary of FDA’s Process

• FDA District Office learns of recall
• District prepares recall information for review by Center and Office of Enforcement
  – Includes a classification recommendation
• FDA formalizes recall by reviewing the information, assessing the health hazard, and classifying the recall
• Firm is notified of the classification and any necessary changes in their recall strategy
Summary of FDA’s Process

- FDA publishes recall information on the FDA internet site and in the Enforcement Report
  - Press Release for Class I recalls and some Class II’s

- FDA provides recall information to other federal and government agencies

- FDA monitors and audits the recall to ensure effectiveness
  - Can include “audit checks” conducted by FDA investigators

- FDA terminates the recall and provides written notification to the recalling firm
21 CFR Part 7: Recalls

Recalls are classified by the FDA to indicate the relative degree of health hazard presented by the product being recalled

- **Class 1** = there is a reasonable chance the device will cause serious adverse health consequences or death

- **Class 2** = possibility that the device may cause temporary or medically reversible adverse health consequences, or there is a remote chance it will cause serious adverse health consequences

- **Class 3** = the device is not likely to cause adverse health consequences

*** FDA determines the classification by conducting a health hazard evaluation as required by 21 CFR Part 7.41
21 CFR Part 806 - History

- **Requires** manufacturers and importers to notify FDA of their recalls

- Effective 5/18/98
  - Prior to this, reporting recalls to FDA was voluntary

- Why? - So that FDA can monitor C&R’s in a more timely and effective manner
21 CFR Part 806

• Report required if correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the act caused by the device which may present a risk to health

• Report is not required if the information was provided to FDA under 21 CFR 803 (Medical Device Reporting)
21 CFR Part 806: Definitions

**Removal** - the physical removal of a device from its point of use to some other location for:

- Repair
- Modification
- Adjustment
- Relabeling
- Destruction
- Inspection
21 CFR Part 806: Definitions

**Correction** means:

- Repair
- Modification
- Adjustment
- Relabeling
- Destruction
- Inspection
  - Including patient monitoring

**without** physically removing the device from its point of use
21 CFR Part 806: Definitions

- Definition of “risk to health” under 21 CFR 806 tracks definition of Class I and Class II recall in 21 CFR 7.3(m)
  - reasonable probability that product will cause serious adverse health consequences or death (Class I), or
  - may cause temporary or medically reversible adverse health consequences or an outcome where probability of serious adverse health consequences is remote (Class II)
Beware….

- You are required to report a correction or removal if correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the act caused by the device which may present a risk to health (class I and II recalls)

- While you do not need to report class III recalls, remember that FDA classifies the recall. You make think it is a class III, but FDA might classify it as a class I
  - You are required to maintain records of corrections and removals you do not report, so expect FDA to review these during an inspection
  - FDA investigators often find corrections and removals that should have been reported but were not

- Take home message – contact your local FDA district recall coordinator to make sure it is really considered a class III
21 CFR Part 806: Requirements

REPORTING

RECORD KEEPING
21 CFR Part 806: Reporting

Manufacturer or importer shall submit a written report to FDA within 10 working days of INITIATING such correction or removal.

– Reduce a risk to health, or
– To remedy a violation of the Act caused by the device which may represent a risk to health
21 CFR Part 806: Reporting

- 21 CFR Part 806.10 specifies the information that needs to be in the report

- Reports should be made to the FDA District Office in which the reporting facility is geographically located
21 CFR Part 806

The following actions are exempt from reporting requirements:

– Market withdrawal
– Routine servicing (scheduled or expected)
– Stock recoveries
– Performance improvements that do not reduce a risk to health or correct a violation of the act
Market Withdrawal

A correction or removal of a distributed product that is not in violation, or when the violation would not be subject to FDA action. For example:

- Replacement of an expired product
- Software upgrade to latest version if not done because of a health hazard
21 CFR Part 806: Definitions

Routine Servicing

Any regularly **scheduled** or **expected** maintenance of a device

Examples: calibration, replacement of batteries (at the end of normal life expectancy), normal wear and tear, etc.

**Unexpected repairs are NOT routine servicing**
Stock Recovery

Removal or correction of a device that has not been marketed or not left the direct control of the firm
21 CFR Part 806: Record Keeping

If not required to report:

- Manufacturer or importer shall keep a record of the correction or removal. 21 CFR Part 806.20(b) lists what shall be in the record.

- The record shall contain justification for not reporting, including conclusions.
21 CFR Part 806: Record Keeping

The manufacturer or importer shall retain records for a period of 2 years beyond the expected life of the device.
21 CFR Part 806

During Establishment Inspections, expect FDA to:

• Ask if there have been any corrections or removals

• Determine if they have been reported

• If not, have you kept records and justifications for not reporting?

• Determine if CA/PA have been effective in correcting the problems
21 CFR Part 806

• Expect FDA to evaluate other corrective actions the firm has initiated that could be considered reportable under 21 CFR 806
  – Correspondence or “Customer Letters”
  – Activities described as “Updates”
  – Review Engineering Change Notices/Orders
21 CFR Part 806
QUESTIONS