Class 2 Recall
Zimmer UNIVERSAL Power System Loaener & Modular Electric/Battery

Date Posted
December 21, 2015

Recall Status
Open

Recall Number
Z-0453-2016

Recall Event ID
7268623

Product Classification
Saw, Powered, And Accessories - Product Code HAB

Product

Code Information
Model # 01-8507-400-10 & Model # 89-8507-400-10

Recalling Firm/Manufacturer
Zimmer, Inc.
1800 W Center St
Warsaw, Indiana 46580-2304

Manufacturer Reason for Recall
The firm identified a malfunction which made it possible for a handpiece to start by itself when the power source is connected.

FDA Determined Cause
DESIGN: Device Design

Action
Zimmer sent an Urgent Medical Device Correction letter dated November 9, 2015, to all affected customers. The letter identified the problem and the action needed to be taken by the customer. 1. Review this notification. 2. You will receive copies of notification sent directly to hospital risk managers and surgeons in your territory. As necessary, review and facilitate understanding of this notification by those entities. 3. Further identify hospital risk managers and/or surgeons in your territory who should also receive notification of this update, and supply the information to the entities you have identified. 4. If after reviewing this notification you have further questions or concerns, please call 330-364-0989 between the hours of 8 a.m. and 5 p.m. EST, Monday through Friday. Zimmer instructed their direct customers that they will upgrade the device with the new electronic during their annual preventative maintenance activities. Until the new upgrade is installed, the firm instructed their customers to follow the Instructions for Use.

Quantity In Commerce
89 units

Distribution
US Distribution to the states of : AR, CA, CO, CT, FL, GA, HI, IL, KS, KY, LA, ME, MI, MN, MO, MS, NC, NE, NJ, NV, NY, OH, PA, RI, SC, TX, UT, VA, WA, WI, WV and WV.

Total Product Life Cycle
TPLC Device Report

1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55

2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

Links on this page: