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

See Related Information [22]

Date Posted	December 21, 2015
Recall Status[1]	Open
Recall Number	Z-0453-2016
Recall Event ID	72688[23]
Product Classification	Saw, Powered, And Accessories[24] - **Product Code** HAB[25]
Product	Zimmer® UNIVERSAL Power System Loaner & Modular Electric/Battery Single Trigger Handpiece. Rx only Made in Switzerland Zimmer /Surgical S.A., Chemin Pre Fleuri 3, C?H-1228 Geneva - Plan Les Quates, Switzerland
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 [2]	DESIGN: Device Design
Action	Zimmer sent an Urgent Medical Device Correction letter dated November 9, 2015, to all affected customers. The letter identified the product 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 WY.
Total Product Life Cycle	TPLC Device Report[26]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[27]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.