Class 2 Device Recall Zimmer/CAS Power Cord, Sesamoid Plasty, NA

See Related Information[22]

Date Initiated by Firm	November 02, 2009
Date Posting Updated	December 22, 2009
Recall Status[1]	Terminated [3] on October 15, 2010
Recall Number	Z-0558-2010
Recall Event ID	53687[23]
510(K)Number	K060336[24] K071714[25] K071929[26]
Product Classification	power cord[27] - **Product Code** HAW[28]
Product	Zimmer/CAS Power Cord, Sesamoid Plasty, NA, Zimmer/CAS, Montreal (Quebec), Canada; REF 20-8000-070-12. The device is the power cord component for the Sesamoid Plasty CAS workstation which connects the workstation to the power mains.
Code Information	Workstation serial numbers SP014, SP015, SP019 through SP022, SP025 through SP033, SP035, SP038, SP039, SP043, SP044, SP047, SP049, SP052, SP057, SP058, SP060, SP061, SP062, SP064, SP065, SP069, SP072, SP074 through SP083, SP089, SP090, SP091, SP093, SP094, SP098, SP099, SP121, SP124, SP125, SP127, SP128, SP131 through SP135, SP151 through SP154, SP157, SP175, SP176, SP183, SP184, SP185, SP190 and SP198.
Recalling Firm/ Manufacturer	Zimmer Inc. 345 E Main St Warsaw IN 46580-2746
For Additional Information Contact	866-978-3801
Manufacturer Reason for Recall	The power cord female receptacle is not recessed sufficiently and may present a shock hazard.
FDA Determined Cause [2]	Device Design
Action	Zimmer sales staff were notified by letter dated 11/2/09 and instructed to locate the units and to upgrade the cords and to notify consignees by copy of a letter addressed to risk managers and dated 11/2/09.
Quantity in Commerce	71
Distribution	Nationwide.
Total Product Life Cycle	TPLC Device Report[29]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[30].
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.