Class 2 Device Recall Computer Assisted Surgical Device

Date Initiated by Firm: February 10, 2013
Create Date: November 28, 2017
Recall Status: Open
Recall Number: Z-0178-2018
Recall Event ID: 77872
510(K) Number: K107191 K092239
Product Classification: Neurological stereotaxic Instrument - Product Code HAW
Product: ROSA Surgical Device 2.5.8
Code Information: Serial No. RO10011, RO10014, RO13023 and RO13027.
Recalling Firm/Manufacturer: Zimmer Biomet, Inc.
1800 W Center St
Warsaw IN 46580-2304
For Additional Information Contact: Kevin Escapule
574-267-8131
Manufacturer Reason for Recall: Issue with optional neuro-endoscopy module detected under specific conditions during internal testing.
FDA Determined Cause: Software design
Action: Field Service Technicians were dispatched to correct units by upgrading the system to ROSA 2.5.7. A further update of ROSA 2.5.8.4. A Field Safety Notice dated 07/10/2013 notifying consignees of a risk in the ROSA system recognized in internal testing. It was suggested that consignees not utilize the neuro-endoscopy module until further notice. The recall notice should have been shared with the appropriate parties and the signed acknowledgement form returned to the recalling firm.
Quantity in Commerce: 22 units (4 US and 18 OUS)
Distribution: AR, OH, MI, and TX
Total Product Life Cycle: TPLC Device Report

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.

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

3 The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database: 510(K)is with Product Code = HAW and Original Applicant = MEDTECH S.A.
510(K)is with Product Code = HAW and Original Applicant = MEDTECH SAS

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=157472
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