Class 2 Device Recall Computer Assisted Surgical Device

See Related Information[22]

Date Initiated by Firm	February 10, 2013
Create Date	November 28, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-0178-2018
Recall Event ID	77672[23]
510(K)Number	K101791[24] K092239[25]
Product Classification	Neurological stereotaxic Instrument[26] - **Product Code** HAW[27]
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 574-267-6131
Manufacturer Reason for Recall	Issue with optional neuro-endoscopy module detected under specific conditions during internal testing.
FDA Determined Cause [2]	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[28]

[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[29].
[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)s with Product Code = HAW and Original Applicant = MEDTECH S.A.[30] 510(K)s with Product Code = HAW and Original Applicant = MEDTECH SAS[31]