Class 2 Device Recall ComputerAssisted Surgical Device

See Related Information [22]

Date Initiated by Firm	July 20, 2016
Create Date	November 21, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-0167-2018
Recall Event ID	78367[23]
510(K)Number	K151359[24]
Product Classification	Neurological stereotaxic Instrument[25] - **Product Code** HAW[26]
Product	ROSA Brain 3.0.0 Usage: The device is intended for the spatial positioning and orientation of instrument holders or tool guides to be used by neurosurgeons to guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode, endoscope). The device is indicated for any neurosurgical procedure in which the use of stereotactic surgery may be appropriate.
Code Information	Serial #'s: BR16004, BR16005, BR16006, BR16009, BR16010, BR16011, BR16012, BR16013, BR16014, BR16015, BR16016, BR16017, BR16018, and , BR16021.
Recalling Firm/ Manufacturer	Zimmer Biomet, Inc. 1800 W Center St Warsaw IN 46580-2304
For Additional Information Contact	Mr. Kevin W. Escapule 574-267-6131
Manufacturer Reason for Recall	Communication errors between ROSANNA BRAIN software, MARIO software and the St¿ubli CS8C controller.
FDA Determined Cause [2]	Software design
Action	This is a retrospective report of a correction initiated on 20-Jul-2016. Customers were informed onsite by field Service Technicians of the planned correction. The software issue described was corrected in the new software version ROSA Brain 3.0.0.20. Field Service Technicians were deployed to the customers locations to perform the system upgrade. .
Quantity in Commerce	18 (14 US and 4 OUS)
Distribution	Worldwide Distribution - US Nationwide in the states of OH, FL, MA, MN, DC, NC, CA, NY, PA and countries of Australia and France
Total Product Life Cycle	TPLC Device Report[27]

[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.