Class 2 Device Recall Computer Assisted Surgical Device

Date Initiated by Firm: July 20, 2016
Create Date: November 21, 2017
Recall Status: Open, Classified
Recall Number: Z-0167-2018
Recall Event ID: 78367
510(K) Number: K151359
Product Classification: Neurological stereotaxic Instrument - Product Code HAW
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 #: BR16004, BR16005, BR16006, BR16009, BR16010, BR16011, BR16012, BR16013, BR16014, BR16015, BR16016, BR16017, BR16018, and BR16021.

Recalling Firm/Manufacturer: Zimmer Biomet, Inc.
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For Additional Information Contact: Mr. Kevin W. Escapule
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Manufacturer Reason for Recall: Communication errors between ROSANNA BRAIN software, MARIO software and the Stylobili CS8C controller.
FDA Determined Cause: 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

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.