Class 2 Device Recall Herga foot switch, a component of ROSA Surgical Device

**Date Initiated by Firm**: January 20, 2016

**Create Date**: September 12, 2017

**Recall Status**: Open, Classified

**Recall Number**: Z-3117-2017

**Recall Event ID**: 77614

**510(K) Number**: K092239, K101791

**Product Classification**: Neurological stereotactic Instrument - Product Code HAW

**Product**: Herga foot switch, model 6289-WS, a component of the ROSA Roboticized Stereotactic Assistant Surgical Device, Model 2.5.8. The firm name on the foot switch label is Herga Electric Limited, Bury, St. Edmunds, Suffolk IP32 6NN. ROSA Surgical Device is a computer-controlled electromechanical arm. It is intended to be used in the operating room for the spatial positioning and orientation of an instrument holder or tool guide. Guidance is based on a pre-operative plan developed with three-dimensional imaging software and uses fiducial markers or optical registration. The system is intended for use by neurosurgeons to guide standard neurological instruments. It is indicated for any neurosurgical condition in which the use of stereotactic surgery may be appropriate.


**Recalling Firm/Manufacturer**: Zimmer Biomet, Inc.
1800 W Center St
Warsaw IN 46580-2304

**For Additional Information Contact**: Kevin W. Escapule
574-267-6131

**Manufacturer Reason for Recall**: Complaints were received reporting the system would freeze/shut down while in Fulgurate mode.

**FDA Determined**: Software design

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=156850
9/19/2017
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Cause
Zimmer Biomet sent an Urgent Medical Device Recall Correction letter dated July 26, 2017, to all affected consignees. The letter identified the product, the problem, and the action to be taken by the customer. Customers were instructed to discontinue use of the affected product for all surgical procedures, notify and ensure affected personnel are aware of the contents, complete the attached Certificate of Acknowledgement and return a digital copy. Customers with questions were instructed to call +33 (0) 467 107740, US customers should call 800-874-7711, ext 9225. The initial correction was conducted by the manufacturer on January 20, 2016 with two of the 32 affected units which were imported into the U.S. being corrected by a customer representative. For questions regarding this recall call 574-267-6131.

Quantity in Commerce
64 devices

Distribution
Worldwide Distribution - US (nationwide) and Internationally to Canada, China, France, Germany, India, Israel, Italy, Russia, Saudi Arabia, Spain and the United Kingdom.

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

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
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