FDA

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

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See Related Information[22]

Date Initiated by Firm	January 20, 2016
Create Date	September 12, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-3117-2017
Recall Event ID	77614[23]
510(K)Number	K092239[24] K101791[25]
Product Classification	Neurological stereotaxic Instrument[26] - **Product Code** HAW[27]
Product	Herga foot switch, model 6289-WS, a component of the ROSA Robotized 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 neurosurgical instruments. It is indicated for any neurosurgical condition in which the use of stereotactic surgery may be appropriate
Code Information	Serial numbers for ROSA devices with the Herga Footswitch in US distribution: Serial No. RO10009, RO10011, RO10014, RO13023, RO13027, RO14033, RO14035, RO14037, RO14038, RO14039, RO14040, RO14041, RO14043, RO15044, RO15045, RO15046, RO15048, RO15050, RO15051, RO15052, RO15053, RO15054, RO15058, RO15059, RO15060, RO15061, RO15062, RO15063, RO15064, RO15067, RO15069, and RO14031. Serial numbers for ROSA devices with the Herga Footswitch in foreign distribution: Serial No. RO08003, RO09004, RO09005, RO10007, RO10010, RO10013, RO11015, RO11016 RO11017, RO12018, RO12019, RO12020, RO12021, RO12022, RO13024 RO13025, RO13026, RO14029, RO14030, RO14032, RO14034, RO14036 RO14042, RO15047, RO15049, RO15055, RO15056, RO15057, RO15065 RO15066, RO15068, and RO15070.
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

Cause [2]	
Action	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 Certificated 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[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]

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