Class 2 Device Recall Medtronic Aptus(TM) HeliFX(TM) Thoracic EndoAnchor(TM) System
HeliFX Guide 42 mm

Date Initiated by Firm September 13, 2017
Create Date September 27, 2017
Recall Status 1 Open 3, Classified
Recall Number Z-3227-2017
Recall Event ID 78127 23
510(K)Number K171427 24
Product Classification Endovascular suturing system 25 - Product Code OTD 26

The Heli-FX EndoAnchor System is intended to provide fixation and sealing between endovascular aortic grafts and the native artery. The Heli-FX System is indicated for use in patients who endovascular grafts have exhibited migration or endoleak, or are at risk for such complications, in whom augmented radial fixation and or sealing is required or regain or maintain adequate aneurysm exclusion.

Code Information UDI 00763000006679, Lot Number 0008674156, UDI 0076300006655, Lot Number 0008674157
Recalling Firm/ Manufacturer Medtronic Vascular, Inc.
3576 Unocal PI
Santa Rosa CA 95403-1774
For Additional Information Contact Kristen Hayward
508-261-8000
Manufacturer Reason for Recall It was determined that the deflection length indicated on the Guide catheter handle does not match the label on the box and sterile packaging for two lots.
FDA Determined Cause 2 Labeling Change Control
Action The firm initiated their recall on September 13, 2017, by letter. The letter requested the consignee take the following actions: 1. Identify and quarantine all unused affected product as listed in your inventory. 2. Return all unused affected list product in your inventory to Medtronic. Contact Medtronic Customer Service at 1-800-854-3570 to initiate a product return and credit. Your local Medtronic Representative can assist you in the return and replacement of this product as necessary. 3. Complete the enclosed Customer Confirmation Certificate and fax it to Medtronic at 651-367-0612 to the attention of Customer Focused Quality or scan and email to RS.CFQFCA@medtronic.com. This notice needs to be passed on to all those who need to be aware within your organization where the potentially affected devices have been transferred. For further questions, please call (508) 261-8000.

Quantity in Commerce 20 units