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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]
Product	Medtronic Aptus Heli-FX Thoracic EndoAnchor System Heli-FX Guide 42 mm, REF HG-18-90-42, STERILE EO, Rx Only 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 00763000006655, Lot Number 0008674157
Recalling Firm/ Manufacturer	Medtronic Vascular, Inc. 3576 Unocal Pl 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