See Related Information 22

Class 2 Device Recall Everflex SelfExpanding Peripheral Stent with Entrust Delivery System

Date Initiated by Firm	November 03, 2017
Create Date	November 29, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-0188-2018
Recall Event ID	78570[23]
PMA Number	P110023S012[24]
Product Classification	Stent, superficial femoral artery[25] - **Product Code** NIP[26]
Product	Everflex Self-Expanding Peripheral Stent with Entrust Delivery System Intended to improve luminal diameter in the treatment of symptomatic de-novo or restenotic lesions up to 140 mm in length in the native Superficial Femoral Artery (SFA) and/or proximal popliteal arteries with reference vessel diameters ranging from 4.5 - 7.5 mm.
Code Information	Model No. EVD35-07-060-120, UDI 00821684051436, Lot No. A476328. Model No. EVD35-07-120-120, UDI 00821684051467, Lot No. A476301.
Recalling Firm/ Manufacturer	Medtronic Inc. 4600 Nathan Ln N Plymouth MN 55442-2890
For Additional Information Contact	Krystin Hayward 508-261-8000
Manufacturer Reason for Recall	Stent length on the label may not match the length of the stent itself.
FDA Determined Cause [2]	Employee error
Action	Medtronic sent an Urgent Medical Device Recall letter on approximately 11/03/2017, via UPS 2-day delivery. Instructions include identify and quarantine all unused affected product in inventory, return all unused affected product, and complete and return the Customer Confirmation Certificate. Customers with questions regarding this communication, please contact your Medtronic Field Representative. For questions regarding this recall call 508-261-8000.
Quantity in Commerce	21 units
Distribution	Nationwide Distribution to AZ, CA, GA, IA, IL, KY, MA, NC, NE, SC, TN, VA
Total Product Life Cycle	TPLC Device Report[27]

[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.