Class 2 Device Recall GrebSet MicroIntroducer Kit

See Related Information[22]

Date Initiated by Firm	January 12, 2017
Create Date	February 23, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-1250-2017
Recall Event ID	76363[23]
510(K)Number	K081846[24]
Product Classification	Catheter, intravascular, diagnostic[25] - **Product Code** DQO[26]
Product	GrebSet Micro-Introducer Kit, model 7941, Sterilized with Ethylene Oxide. Product Usage: The GrebSet micro-introducer kit is intended to facilitate the percutaneous placement of guidewires in the vascular system and for delivery of contrast media to vascular sites.
Code Information	Lot Numbers: 581212, 584392, 594115, 597202
Recalling Firm/ Manufacturer	Vascular Solutions, Inc. 6464 Sycamore Ct N Maple Grove MN 55369-6032
For Additional Information Contact	VSIs Customer Service Dept. 763-656-4300
Manufacturer Reason for Recall	Four Lots of GrebSet Micro-introducer Kits, model 7941, contain guidewires that have a shelf life shorter than the kit expiration date.
FDA Determined Cause [2]	Error in labeling
Action	Consignees were sent on 1/12/2017 a Vascular Solutions "Urgent Medical Device Recall" letter dated January 11th, 2017. The letter identified the problem and product involved in the recall. The letter provided "Your Immediate Action Is Required". This included to remove the product from inventory and to complete and return the VSI's Account Inventory Form to VSIs Customer Service Dept.
Quantity in Commerce	633
Distribution	US Nationwide Distribution in the states of NH, ME, VT, NY, LA, MS, AL CA, IA, WA, OR, MD, DE, PA, NJ, ID, TX, OK, MO, WI, GA, FL, AR, OH, AZ.
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. Learn more about medical device recalls[28].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.