Class 2 Device Recall THERMOCOOL SMARTTOUCH NAVIGATION Catheter

Date Posted: October 27, 2014
Recall Status: Open
Recall Number: Z-0139-2015
Recall Event ID: 69532
Premarket Approval (PMA) Numbers: P030034, P040036
Product Classification: Cardiac Ablation Percutaneous Catheter - Product Code LPB

Product: ThermoCool SmartTouch Navigation Catheters, Catalog No. D132701, D132702, D132703, D132704, D132705, D133601, D133602, D133603.

Code Information: Catalog No. D132701, D132702, D132703, D132704, D132705, D133601, D133602, D133603, All Lots manufactured from launch (Dec 2010)

Recalling Firm/Manufacturer: Biosense Webster, Inc.
15715 Arrow Hwy
Irwindale, California 91706-2005

Manufacturer Reason for Recall: The recall was initiated because Biosense Webster is providing additional labeling for the safe and effective use of the ThermoCool SmartTouch Catheter.

FDA Determined Cause: TRAINING: Use Error

Action: A customer notification letter dated October 19, 2014, will be sent to all customers who purchased the Biosense Webster's ThermoCool SmartTouch Catheter Family. The letter informs the customers of the additional information for the safe and effective use of the ThermoCool SmartTouch Catheter, which will be included in the updated labeling. The letter informs the customers of the problems identified and the actions to be taken. Customers with questions related to the recall letter are instructed to contact their Biosense Webster sales representative or call (956) 475-7823, Monday through Friday from 7am to 6pm EST.

Quantity in Commerce: 173,329 units total (21,812 units in US)

Distribution: Nationwide Distribution

Total Product Life Cycle: 28 months


Links on this page:

11/10/2014