FDA

Class 2 Device Recall Stryker Sustainability Solutions Reprocessed BW Lasso 2515 NAV eco Variable Diagnostic EP Catheters,

See Related Information[22]

Class 2 Device Recall Stryker Sustainability Solutions Reprocessed BW Lasso 2515 NAV eco Variable Diagnostic EP Catheters,

Date Initiated by Firm	January 02, 2018
Create Date	March 06, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-0917-2018
Recall Event ID	79087[23]
510(K)Number	K112292[24]
Product Classification	Catheter, recording, electrode, reprocessed[25] - **Product Code** NLH[26]
Product	Stryker Sustainability Solutions Reprocessed BW Lasso 2515 NAV eco Variable Diagnostic EP Catheters, Ref D134302, Sterile, Rx. The Reprocessed 2515 NAV eco Variable Electrophysiology (EP) Catheters are indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. recording or stimulation only. They are designed to obtain electrograms in the atrial regions of the heart. The Reprocessed 2515 NAV eco Variable EP Catheters provide location information when used with compatible CARTO EP Navigation Systems version 2.3 or higher.
Code Information	Serial numbers 2468846, 2468849, 2509029, 2489074, 2491174, 2500529, 2465989, and 2500528
Recalling Firm/ Manufacturer	Stryker Sustainability Solutions 1810 W Drake Dr Tempe AZ 85283-4327
For Additional Information Contact	Kara Madsen 888-888-3433
Manufacturer Reason for Recall	An EEPROM chip error code may occur when the catheters are used with CARTO EP Navigation Systems.
FDA Determined Cause [2]	Device Design
Action	Stryker sent an Urgent Medical Device Recall letter dated January 2, 2018, explains the reason for recall, risk to health, and instructs them to discontinue use of the affected products. The customer is to check their inventory for the affected serial numbers provided in the attachment and complete the recall effectiveness check form to indicate the amount of product in inventory. Return instructions are provided. For further questions, please call (888) 763-8803.
Quantity in Commerce	8 devices
Distribution	USA (nationwide) Distribution was made to medical facilities in AZ, CA, CT, FL, GA, IL, KS,