Class 2 Device Recall BW Lasso 2515 ANV eco Variable Diagnostic EP Catheter

Date Initiated by Firm: December 17, 2018
Create Date: January 23, 2019
Recall Status: Open, Classified
Recall Number: Z-0766-2019
Recall Event ID: 8188023
510(K) Number: K1122824
Product Classification: Catheter, recording, electrode, reprocessed - Product Code NLH
Product: BW Lasso 2515 ANV eco Variable Diagnostic EP Catheter, REF D134301

Diagnostic electrophysiology (EP) catheters are specially designed electrode catheters that transmit electrical impulses and can be positioned for endocardial recording or stimulation.

Code Information: Lot Codes: 2674940 2724318 2761521 2794036 2879309 2918829 2877298 2724320 2763683 2794073 2879312 2920167 2767324 2726887 2767521 2794191 2867266 2925629 2877325 2727015 2767528 2804281 2887691 2925630 2767326 2772016 2767537 2843017 2889131 2925632 2677327 2732728 2777174 2843547 2862701 2925633 2677328 2736609 2777175 2862775 2893277 2930750 2677331 2742516 2777165 2862776 2869226 2930753 2767338 2742579 2777166 2869100 2869229 2941324 2767399 2742580 2777187 2871151 2898832 2970121 2683262 2748664 286407 2873812 2869336 2970300 2692529 2746673 2788426 2873898 2868840 2970301 2692536 2751680 2786502 2873899 2868845 2970302 2719705 2758589 2786506 2873824 2898846 2986705 2719707 2755641 2786537 2873935 2906003 2993057 2724210 2756564 2786538 2875420 2906077 3002363 2724823 2761520 2786538 2876614 2917998 3002364 3007144

Recalling Firm/Manufacturer: Stryker Sustainability Solutions
1810 W Drake Dr
Tempe AZ 85283-4327

Manufacturer Reason for Recall: Stryker's Sustainability Solutions division (SSS) has received an increase in reports indicating that an EEPROM chip error code may occur when Reprocessed 2515 NAV eco Variable Electrophysiology (EP) Catheters are used with CARTO(R) EP Navigation Systems.

FDA Determined Cause: Process change control

Action: The firm, Stryker, sent an "URGENT MEDICAL DEVICE RECALL" Customer Notification Letter and attached Recall Effectiveness Check Form to Stryker Sustainability Solutions (SSS) sales representatives and international Stryker divisions to notify affected customers.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=170204 05/02/2019