FDA

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

See Related Information[22]

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[1]	Open[3], Classified
Recall Number	Z-0766-2019
Recall Event ID	81880[23]
510(K)Number	K112292[24]
Product Classification	Catheter, recording, electrode, reprocessed[25] - **Product Code** NLH[26]
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 2677298 2724320 2763683 2794073 2879312 2920167 2677324 2726887 2767521 2794191 2887266 2925629 2677325 2727015 2767528 2804281 2887691 2925630 2677326 2727016 2767537 2843017 2889131 2925632 2677327 2732728 2777174 2843547 2892701 2925633 2677328 2736609 2777175 2862775 2893277 2930750 2677331 2742516 2777185 2862776 2896226 2930753 2677398 2742579 2777186 2869100 2896229 2941324 2677399 2742580 2777187 2871151 2898832 2970121 2683282 2746664 2786407 2873812 2898836 2970300 2692529 2746673 2786426 2873898 2898840 2970301 2692536 2751680 2786502 2873899 2898845 2970302 2719705 2755589 2786506 2873924 2898846 2986705 2719707 2755641 2786537 2873935 2906003 2993057 2724210 2755694 2786538 2875420 2906077 3002383 2724283 2761520 2786568 2876114 2917968 3002384 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 [2]	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