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

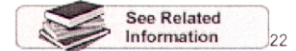


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**Class 2 Device Recall Stryker  
 Sustainability Solutions  
 Reprocessed BW Lasso 2515 NAV  
 eco Variable Diagnostic EP  
 Catheters,**



|   |   |
|---|---|
| <b>Date Initiated by Firm</b>                 | January 02, 2018  |
| <b>Create Date</b>                            | March 06, 2018  |
| <b>Recall Status<sup>1</sup></b>              | Open <sup>3</sup> , Classified  |
| <b>Recall Number</b>                          | Z-0917-2018   |
| <b>Recall Event ID</b>                        | 79087 <sup>23</sup>   |
| <b>510(K)Number</b>                           | <a href="#">K112292<sup>24</sup></a>  |
| <b>Product Classification</b>                 | Catheter, recording, electrode, reprocessed <sup>25</sup> - <b>Product Code NLH<sup>26</sup></b>  |
| <b>Product</b>                                | <p>Stryker Sustainability Solutions Reprocessed BW Lasso 2515 NAV eco Variable Diagnostic EP Catheters, Ref D134302, Sterile, Rx.</p> <p>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.</p> |
| <b>Code Information</b>                       | Serial numbers 2468846, 2468849, 2509029, 2489074, 2491174, 2500529, 2465989, and 2500528   |
| <b>Recalling Firm/<br/>Manufacturer</b>       | Stryker Sustainability Solutions<br>1810 W Drake Dr<br>Tempe AZ 85283-4327  |
| <b>For Additional<br/>Information Contact</b> | Kara Madsen<br>888-888-3433   |
| <b>Manufacturer Reason<br/>for Recall</b>     | An EEPROM chip error code may occur when the catheters are used with CARTO EP Navigation Systems.   |
| <b>FDA Determined<br/>Cause <sup>2</sup></b>  | Device Design   |
| <b>Action</b>                                 | 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.  |
| <b>Quantity in Commerce</b>                   | 8 devices   |
| <b>Distribution</b>                           | USA (nationwide) Distribution was made to medical facilities in AZ, CA, CT, FL, GA, IL, KS,   |