Class 2 Device Recall Stryker Sustainability Solutions

See Related Information[22]

Recall Date	May 23, 2016
Recall Status[1]	Open
Recall Number	Z-1708-2016
Recall Event ID	73983[23]
510(K)Number	K012708[24]
Product Classification	Catheter, recording, electrode, reprocessed[25] - **Product Code** NLH[26]
Product	Reprocessed Daig Supreme Fixed Curve Diagnostic Electrophysiology Catheters; Model #: 401450, 401877. Indicated for temporary intracardiac sensing, recording, stimulation, and electrophysiology mapping of cardiac structures.
Code Information	Catalog Number: 401450 Lot Number: 2561683E Expiration Date: 5/13/2017 Catalog Number: 401877 Lot Number: 2555866E Expiration Date: 5/6/2017
Recalling Firm/ Manufacturer	Stryker Sustainability Solutions 1810 W Drake Dr Tempe AZ 85283-4327
For Additional Information Contact	888-888-3433
Manufacturer Reason for Recall	Mislabeled for size
FDA Determined Cause [2]	Under Investigation by firm
Action	The firm sent out customer notification letters on 04/28/16. Customers are instructed to discontinue the use of affected lots of recalled product. Other EP Catheters reprocessed by Stryker Sustainability Solutions should be considered as alternatives. A Recall Effectiveness Check Form including the quantity of affected devices shipped to facility is enclosed. Please complete the Recall Effectiveness Check Form and indicate if any devices from the affected lots remain in your inventory. This form needs to be completed even if no affected product is found. Please return the completed and signed Recall Effectiveness Check Form to your local Stryker Sustainability Sales Representative or email to SSSPFA@stryker.com or mail to: Stryker Sustainability Solutions 1810 West Drake Drive Tempe, AZ, 85283 Attn: Jodie Rueckert If the form indicates that affected devices remain in inventory, a prepaid shipping label will be issued for the return of the product. Customers will receive a credit for all affected devices returned. Adverse reactions or quality problems experienced with the use of this product may be reported to: - Stryker Sustainability Solutions Complaint Hotline: +1(888) 888-3433 X5555 - http://www.stryker.com/productexperience/ - The FDAs MedWatch Adverse Event Reporting program either online, by regular mail, or by fax. On 05/12/16 the firm sent out a clarification letter to emphasize that use of affected lots of product should be discontinued. In addition, SSS would like to note that, use of devices larger than expected may result in excess force applied to the blood vessel. The risk to the patient can vary from a

	prolongation in procedure time, vessel rupture, organ damage or other unforeseen consequences. Some of these injuries may require surgery or other procedures to remedy. Any questions contact the Stryker Sustainability Solutions Sales Representative or Regulatory Affairs.
Quantity in Commerce	18 devices
Distribution	Distributed in the state of NY and the country of Canada.
Total Product Life Cycle	TPLC Device Report[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database 510(K)s with Product Code = NLH and Original Applicant = ALLIANCE MEDICAL CORP.[29]

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22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=73983
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K012708
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