Class 2 Device Recall Stryker FlowPort II Adapter

See Related Information[22]

Date Posted	June 03, 2016
Recall Status[1]	Terminated on June 03, 2016
Recall Number	Z-1910-2016
Recall Event ID	74070[23]
Product Classification	OR - Orthopedic[24] - **Product Code** NBH[25]
Product	Stryker FlowPort II Adapter: Model number: 00CAT00778 The FlowPort II Adapter is intended to connect the FlowPort II Cannulas to commercially available, 4mm arthroscopes in surgical procedures.
Code Information	Lot Numbers Affected: 13604
Recalling Firm/ Manufacturer	Stryker Corporation 5900 Optical Ct San Jose CA 95138-1400
For Additional Information Contact	Michael Hilldoerfer 408-754-2664
Manufacturer Reason for Recall	Complaints were received for the Stryker FlowPort II Adapter, and investigation found that the scope sat in the adapter 180 degrees in the wrong direction
FDA Determined Cause [2]	Device Design
Action	A recall letter was not sent as all affected devices have been returned. A ship hold was placed on the device on October 16, 2015.
Quantity in Commerce	21 units
Distribution	GA, UT, MD, NJ, MT
Total Product Life Cycle	TPLC Device Report[26]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[27]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm