FDA

Class 2 Device Recall StrykeFlow 2 suction/irrigator

See Related Information[22]

Date Initiated by Firm	November 17, 2017
Create Date	March 02, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-0835-2018
Recall Event ID	78668[23]
510(K)Number	K934094[24] K954726[25]
Product Classification	Laparoscope, general & plastic surgery[26] - **Product Code** GCJ[27]
Product	*StrykeFlow 2 System, labeled sterile. Includes the following:* a. STRYKER LAPAROSCOPIC SUCTION IRRIGATOR, Suction/Irrigator 2 (Model 0250070500); b. STRYKER STRYKEFLOW SUCTION IRRIGATOR, Disposable Strykeflow S/I Tip (Model 0250070505); c. STRYKER STRYKEFLOW SUCTION IRRIGATOR, Strykeflow 2 with Tip (Model 0250070520) STRYKER LAPAROSCOPIC SUCTION IRRIGATOR
Code Information	a. Model 0250070500, Product Code GCJ, UDI 07613327061390, Lot No. 17275FG2, 17276FG2, 17277FG2, 17278FG2, 17279FG2, 17280FG2, 17283FG2, 17284FG2, 17285FG2, 17286FG2, 17289FG2, 17290FG2, 17291FG2, 17292FG2, 17293FG2, 17294FG2, 17297FG2, 17299FG2, 17301FG2); 0250070505, 0250070520; , b. Model 0250070505, Product Code GCX, UDI 07613327061406, Lot No. 17294FG2; , c. Model 0250070520, Product Code GCX, UDI 07613327061369, Lot No. 17282FG2, 17283FG2, 17286FG2, 17289FG2, 17290FG2, 17292FG2, 17293FG2, 17294FG2, 17296FG2, 17297FG2, 17298FG2, 17299FG2, 17300FG2, 17301FG2, 17302FG2
Recalling Firm/ Manufacturer	Stryker Corporation 5900 Optical Ct San Jose CA 95138-1400
Manufacturer Reason for Recall	Routine bioburden testing of certain lots were found to have levels higher than internal acceptable rates.
FDA Determined Cause [2]	Under Investigation by firm
Action	*On about 11/17/2017 letters were sent by certified mail with tracking information to all* domestic accounts and International Stryker sites were notified by email. Instructions include to inform individuals who need to be aware of the device recall, examine all stock areas and/or operating room storage for affected product quarantine and discontinue use of the recalled devices, complete the acknowledgement form, and if affected product is found contact Stryker customer service at 1-800-624-4422 (Option 3) or email endocustomersupport@stryker.com to arrange for product return.
Quantity in Commerce	60,753 units total
Distribution	Distributed domestically to . Distributed internationally to Australia and Mexico.