Class 2 Device Recall | Cardiopulmonary Bypass Catheter Cannula and Tubing

Date Initiated by Firm: June 09, 2017
Create Date: August 10, 2017
Recall Status: Open, Classified
Recall Number: Z-2871-2017
Recall Event ID: 77699
510(K) Number: K943934

Product Classification: Catheter, cannula and tubing, vascular, cardiopulmonary bypass - Product Code DWE

Product: Sorin Group Aortic Arch Cannula, 7 mm x 10 in x 3/8 in, Rx Only, Sterile

Product Usage:
The Aortic Arch Cannulae are indicated for use in perfusion of the ascending aorta during cardiopulmonary bypass surgery.

Code Information:

Recalling Firm/Manufacturer: Sorin Group USA, Inc.
14401 W 65th Way
Arvada CO 80004-3503

For Additional Information Contact: Joan Ceasar
281-228-7260

Manufacturer Reason for Recall: Identification of excess plastic on the tip of the cannula.

FDA Determined Cause: Process control

Action: LivaNova sent an Urgent Medical Device letter dated June 16, 2017 to affected customers via certified mail or e-mail. The letter identified the affected product, problem and actions to be taken. The notice instructs customers to remove all recalled product from inventory and contact LivaNova Customer Support at 800-650-2623 to arrange for product return and replacement.

Quantity in Commerce: 105,770 units

Distribution: Worldwide Distribution - US Nationwide in the states of: AR, AZ, CA, GA, IL, IN, KS, MI, MN, MO, NC, NE, NY, OK, PA, SD, TX, & VA. and foreign countries of: Canada, Iran, Mexico, & New Zealand.

Total Product Life Cycle: TPLC Device Report

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=157559
8/14/2017