Class 2 Device Recall Aortic Arch Cannula

See Related Information 22

Date Initiated by Firm	August 12, 2016
Create Date	September 08, 2016
Recall Status[1]	Open[3], Classified
Recall Number	Z-2756-2016
Recall Event ID	74934[23]
510(K)Number	K943934[24]
Product Classification	Catheter, cannula and tubing, vascular, cardiopulmonary bypass[25] - **Product Code** DWF[26]
Product	Aortic Arch Cannula and Coronary Artery Perfusion Cannula with Ballon (part number NA-55X6). The Aortic Arch Cannulae are designed to be used in the extracorporeal circuit during cardiopulmonary bypass surgery. The cannula consists of varying lengths of non-wire reinforced (flexible) polyvinyl chloride tubing that terminates in an angled tip. These devices come in direct contact with the central circulatory system but they are not intended to control, diagnose, monitor or correct a defect. The Aortic Arch Cannulae are designed to be used in the extracorporeal circuit during cardiopulmonary bypass surgery. The cannula consists of varying lengths of non-wire reinforced (flexible) polyvinyl chloride tubing that terminates in an angled tip
Code Information	Lot Numbers: 1526500032, 1529300026, 1602600042.
Recalling Firm/ Manufacturer	Sorin Group USA, Inc. 14401 W 65th Way Arvada CO 80004-3503
For Additional Information Contact	Carrie Wood 303-467-6306
Manufacturer Reason for Recall	Sorin Group USA, Inc. announces a voluntary field for the Aortic Arch Cannula and Coronary Artery Perfusion Cannula With Ballon because the tip of the cannula should be bent at either a 45 or 90 degree angle. Samples have been returned where the angle of the tip is less than the requirement.
FDA Determined Cause [2]	Process control
Action	LivaNova issued an Urgent Safety Alert letter via certified mail on August 12, 2016 to all affected customers. The letter instructed customers to check their inventory to determine if the Cannulae belongs to the product code and lots listed. If the customer does not have any of the products described in the communication, please complete the response form below and return it per the instructions indicated on the form; otherwise, please check the tip angle to determine if it is conforming to specifications. If specification is not met, please file a complaint through your normal process whether you decide to keep it and use it or return the product to Sorin Group; if you are not willing to use it, return the affected parts to Sorin Group USA. Please contact Customer Service 1-S00-650-2623 or email CustomerService@livanova.com to have a Return Material Authorization (RMA) issued. Complete the Customer Response Form attached to this letter to acknowledge receipt of this letter. Please return this form no later than September 15, 2016. For questions regarding this