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Class 2 Device Recall FFR LinkFFR Signal Processing Module

Date Initiated by Firm  May 15, 2017
Create Date  September 13, 2017
Recall Status  Open, Classified
Recall Number  Z-3132-2017
Recall Event ID  77444
510(k) Number  K170204
Product Classification  Transmitters and receivers, physiological signal, radiofrequency - Product Code DRG
Product  FFR Link-FFR Signal Processing Module, Material Number H7495651000
It is intended to condition physiological signals from measuring devices (BSC Pressure Guidewire or an external pressure transducer), transmit and receive via radiofrequency, and recondition the signals so they can be displayed on and/or recorded in a receiving device (iLab POLARIS Multi-Modality Guidance System or other monitoring device). The physiological signals can also be distributed by cable
Code Information  Lot/Batch No. (Exp Date): SPM01975 (09/05/2044), SPM00890 (09/27/2043), SPM01616 (08/28/2044)
Recalling Firm/Manufacturer  Boston Scientific Corporation
100 Boston Scientific Way
Marlborough MA 01752-1234
For Additional Information Contact  Nicole Pshon
763-494-1133
Manufacturer Reason for Recall  The device history record (DHR) was missing its test documentation for final HIPOT (high potential) electrical testing.
FDA Determined Cause  Unknown/Undetermined by firm
Quantity in Commerce  3
Distribution  US Distribution to one customer in Missouri.
Total Product Life Cycle  TPLC Device Report

1 A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls.
2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=156068  9/19/2017