FDA

Class 2 Device Recall FFR LinkFFR Signal Processing Module

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See Related Information[22]

Date Initiated by Firm	May 15, 2017
Create Date	September 13, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-3132-2017
Recall Event ID	77444[23]
510(K)Number	K170204[24]
Product Classification	Transmitters and receivers, physiological signal, radiofrequency[25] - **Product Code** DRG[26]
Product	FFR Link-FFR Signal Processing Module, Material Number H7495551000 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 (06/28/2044)
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 [2]	Unknown/Undetermined by firm
Action	Boston Scientific sent an Important Medical Device Information letter dated May 30, 2017, to their affected consignee. On May 15, 2017, Boston Scientific visited the consignee and exchanged the affected device for a device that met specifications. The letter requested a response form be completed and returned. For questions customers should call 763-494-1133.
Quantity in Commerce	3
Distribution	US Distribution to one customer in Missouri.
Total Product Life Cycle	TPLC Device Report[27]

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[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[28].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.