FDA

Class 2 Device Recall SQRX 1010 Pulse Generator

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See Related Information[22]

Date Initiated by Firm	June 29, 2017
Create Date	August 16, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-3039-2017
Recall Event ID	77803[23]
PMA Number	P110042[24]
Product Classification	Implantable cardioverter defibrillator (non-CRT)[25] - **Product Code** LWS[26]
Product	SQ-RX 1010 Pulse Generator, Rx. Product Usage: The S-ICD system is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing
Code Information	All serial numbers
Recalling Firm/ Manufacturer	Boston Scientific Corporation 4100 Hamline Ave N Saint Paul MN 55112-5700
For Additional Information Contact	United States Technical Services 800-227-3422
Manufacturer Reason for Recall	The device can deliver an atypical amount of energy due to memory corruption inside the device.
FDA Determined Cause [2]	Software design
Action	The firm issued notifications dated June, 2017, beginning 6/29/2017 to physicians (implanting and patient follow-up physicians) via hand delivery by their sales representatives. The firm estimated approximately 30% of the U.S. physicians would be receiving the notification via hand delivery. Hand delivery by affiliates in foreign countries to customers began approximately 6/30/2017. Overnight mail letters were issued to the U.S. and foreign physicians starting on/about 7/7/2017 who did not receive hand- delivered notifications.
Quantity in Commerce	Approximately 12,450 devices
Distribution	Worldwide - US Nationwide distribution, including Puerto Rico, U.S. Virgin Island, and Guam, There was also worldwide foreign distribution, including Canada.
Total Product Life Cycle	TPLC Device Report[27]