Class 2 Device Recall SQRX 1010 Pulse Generator

Date Initiated by Firm: June 29, 2017
Create Date: August 16, 2017
Recall Status: Open, Classified
Recall Number: Z-3039-2017
Recall Event ID: 7780323
PMA Number: P110042
Product Classification: Implantable cardioverter defibrillator (non-CRT) - Product Code LWS
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.

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:
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

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=157929 8/18/2017