FDA

Class 2 Device Recall Platinium VR DF4 1240

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See Related Information[22]

Date Initiated by Firm	July 24, 2017
Create Date	September 28, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-3231-2017
Recall Event ID	77983[23]
PMA Number	P980049[24]
Product Classification	Defibrillator, implantable, dual-chamber[25] - **Product Code** MRM[26]
Product	Platinium VR DF4 1240, Model Number TDF035U, UDI/GTIN 08031527015460, Implantable cardioverter defibrillator, Biventricular or ventricular antitachycardia pacing, Dual or single chamber arrhythmia detection Product Usage: PLATINIUM VR is indicated for use in patients who are at high risk of sudden cardiac death due to ventricular tachyarrhythmias and who have experienced one of the following situations: - Survival of at least one episode of cardiac arrest (manifested by the loss of consciousness) due to ventricular tachyarrhythmia, - Recurrent, poorly tolerated sustained ventricular tachycardia (VT).
Code Information	All Serial Numbers
Recalling Firm/ Manufacturer	Sorin Group Italia SRL - CRF Via Crescentino Saluggia, VC Italy
Manufacturer Reason for Recall	There is a possibility of overconsumption of certain PLATINIUM Implantable Cardiac Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) following an ElectroStatic Discharge (ESD) during the implant surgery or a Magnetic Resonance Imaging (MRI) scan, and what actions to take.
FDA Determined Cause [2]	Software design
Action	LivaNova issued a communication to physicians treating patients implanted with the products in scope in the form of a customer letter beginning July 24, 2017. The letter instructs users to do the following: 1. In order to mitigate the potential risks associated with both triggering events (ESD at implant or MRI scan), LivaNova recommends physicians follow the patients at the periodicity already stated in the implant manual, especially: " Before the patient is discharged and at each subsequent follow-up, it is advisable to check the battery status and the occurrence of system warnings; " It is recommended that a routine follow-up examination be done one month after discharge, and then every three months until the device nears the replacement date.
Quantity in Commerce	72 units
Distribution	US Nationwide Distribution