Class 2 Device Recall Platinium DR DF4 1540

Date Initiated by Firm: July 24, 2017
Create Date: September 28, 2017
Recall Status: Open, Classified
Recall Number: Z-3232-2017
Recall Event ID: 77982
PMA Number: P9800409
Product Classification: Defibrillator, implantable, dual-chamber - Product Code MRM
Product: Platinium DR DF4 1540, Model Number TDF036U, UDI/GTIN 08031527015477,
Implantable cardioverter defibrillator,
Biventricular or ventricular antitachycardia pacing,
Dual or single chamber arrhythmia detection

Product Usage:
PLATINUM 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 PLATINUM Implantable Cardiac
Defibrillators (ICDs) and Cardiac ResynchronizationTherapy 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: 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: 86 units
Distribution: US Nationwide Distribution

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=158443
10/3/2017