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Class 2 Device Recall Platinum DR 1510

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Class 2 Device Recall Platinum DR 1510



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|---|--|
| Date Initiated by Firm | July 24, 2017 |
| Create Date | September 28, 2017 |
| Recall Status¹ | Open ³ , Classified |
| Recall Number | Z-3229-2017 |
| Recall Event ID | <u>77983</u> ²³ |
| PMA Number | <u>P980049</u> ²⁴ |
| Product Classification | <u>Defibrillator, implantable, dual-chamber</u> ²⁵ - Product Code <u>MRM</u> ²⁶ |
| Product | <p>Platinum DR 1510, Model Number TDF032U, UDI/GTIN 08031527015521, Implantable cardioverter defibrillator, Biventricular or ventricular antitachycardia pacing, Dual or single chamber arrhythmia detection</p> <p>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).</p> |
| 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 Cause² | 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 | 206 units |
| Distribution | US Nationwide Distribution |