FDA

See Related Information [22]

Class 1 Device Recall SPHERA, Dual chamber pacemaker

Date Initiated by Firm	January 17, 2019
Create Date	February 14, 2019
Recall Status[1]	Open[3], Classified
Recall Number	Z-0810-2019
Recall Event ID	81945[23]
PMA Number	P980035[24]
Product Classification	Pulse generator, permanent, implantable[25] - **Product Code** NVZ[26]
Product	Medtronic implantable pulse generator. Sphera DR MRI SureScan, Dual chamber rate responsive pacemaker (DDDR) (a) Model Number SPDR01 (b) Model Number SPDRL1
Code Information	RELIA, Dual chamber pacemaker (VDD). (a) Model Number RED01, GTIN 00643169709003, All Serial Numbers. (b) Model Number REDR01, GTIN 00643169708990, 00643169969742, All Serial Numbers. (c) Model Number REVDD01, GTIN: 00643169709010, 00643169969773, All Serial Numbers
Recalling Firm/ Manufacturer	Medtronic Inc., Cardiac Rhythm and Heart Failure (CRHF) 8200 Coral Sea St Ne Mounds View MN 55112-4391
For Additional Information Contact	Technical Services 800-505-4636
Manufacturer Reason for Recall	A subset of Medtronic dual chamber pacemakers distributed worldwide between 10 March 2017 and 7 January 2019 under the brand names Adapta, Versa, and Sensia when programmed to a dual chamber mode with atrial-sensing, may experience a circuit error that affects device functionality.
FDA Determined Cause [2]	Component design/selection
Action	In the US, beginning 17-Jan-2019, Medtronic Field Representatives hand deliver an FCA Notification Letter to consignees including implanting and follow-up physicians. In consultation with an Independent Physician Quality Panel (IPQP), patient management recommendations were provided with the FCA Notification letter to ensure patient safety. Medtronic Field Representatives will hand deliver an additional Supplemental Letter with the Urgent Medical Device Recall letter to a subset of physicians with patients whose device has shown evidence of a pacing pause that is potentially related to this circuit error. Consignees will be asked to return all unused and unopened affected product to Medtronic.