FDA

Class 1 Device Recall Visia AF MRI VR SureScan ICD,

See Related Information[22]

Date Initiated by Firm	December 19, 2017
Date Posted	February 01, 2018
***Recall Status*[1]**	*Open*[3], *Classified*
Recall Number	Z-0588-2018
Recall Event ID	78888[23]
PMA Number	P980016S586[24] P980016S551[25]
Product Classification	Implantable cardioverter defibrillator (non-CRT)[26] - **Product Code** LWS[27]
Product	*Implantable Cardioverter Defibrillators (ICDs), Visia AF MRI. Labeled as the following:* a. Visia AF MRI VR SureScan ICD DF1 (Product No. DVFB1D1); b. Visia AF MRI VR SureScan ICD DF4 (Product No. DVFB1D4)
Code Information	a. Product No. DVFB1D1: UDI 00643169717213 (Serial No. CWG200402H); , b. Product No. DVFB1D4: UDI 00643169566422 (Serial No. PKX202448H, PKX205417H, PKX205779H, PKX209277H), 00643169929913 (Serial No. PKX212710H, PKX213420H)
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	800-723-4636
Manufacturer Reason for Recall	May fail to deliver therapy. Possible prevention of high and low voltage therapy in Medtronic Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillator (CRT-D).
FDA Determined Cause [2]	Process design
Action	On 12/19/2017, Medtronic verbally notified consignees and retrieved eight devices at sites that had affected inventory on hand. On 01/22/2018, Medtronic provided a recall notification letter to physicians following 48 patients implanted with affected devices and risk managers of those medical facilities, recommending that physicians strongly consider prophylactic device replacement for patients implanted with an affected device. Medtronic Technical Services is available to assist physicians with questions at 800-723-4636. Medtronic Patient Service is available to assist patients at 800-551-5544 (Monday-Friday, 8am-5pm Central Time).
Quantity in Commerce	48 devices total
Distribution	US Nationwide Distribution.
Total Product Life Cycle	TPLC Device Report[28]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA