



September 27, 2013

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

Ms. Dianna Johannson  
Sr. Pr. Regulatory Affairs Specialist  
Medtronic, Inc.  
8200 Coral Sea Street  
Moundsview, MN 55112

Re: P890003/S280  
MyCareLink Patient Monitor Models 24950, 24951, and 24955

P010031/S386

InSync III Marquis Model 7279, InSync Marquis Model 7277, InSync Maximo Model 7304, Insync II Protect Model 7295; Brava CRT-D Models DTBC1D1, DTBC1D4; Concerto ICD Model C154DWK; Concerto II CRT-D Model D274TRK; Consulta ICD Models D204TRM, D224TRK; Maximo II CRT-D Models D264TRM, D284TRK; Protecta CRT-D Models D334TRG, D334TRM; Protecta XT CRT-D Models D314TRG, D314TRM; Viva S CRT-D Models DTBB1D1, DTBB1D4; Viva XT CRT-D Models DTBA1D1, DTBA1D4

P980035/S338

Adapta, Versa, Sensia IPG Models ADD01, ADDR01, ADDR03, ADDR06, ADDR11, ADDR51, ADSR01, ADSR03, ADSR06, ADVDD01, SED01, SEDR01, SEDRL1, SES01, SESR01, VEDR01; Advisa DR IPG Model A4DR01; Advisa DR MRI IPG Model A2DR01; EnPulse E1 IPG Models E1DR01, E1DR03, E1DR06, E1DR21; EnPulse E2 IPG Models E2D01, E2D03, E2DR01, E2DR03, E2DR06, E2DR21, E2DR33, E2SR01, E2SR03, E2SR06, E2VDD01; EnRhythm IPG Model P1501DR; Kappa D (Kappa 700) IPG Models KD701, KD703, KD706; Kappa D (Kappa 900) IPG Models KD901, KD903, KD906; Kappa DR (Kappa 650) IPG Models KDR651, KDR653, KDR656; Kappa DR (Kappa 700/600) IPG Models KDR600, KDR601, KDR603, KDR606, KDR701, KDR703, KDR706, KDR721, KDR731, KDR733; Kappa DR (Kappa 900/800) IPG Models KDR801, KDR803, KDR806, KDR901, KDR903, KDR906, KDR921, KDR931, KDR933; Kappa SR (Kappa 700) IPG Models KSR701, KSR703, KSR706; Kappa SR (Kappa 900) IPG Models KSR901, KSR903, KSR906; Kappa VDD (Kappa 700) IPG Models KVDD701, KVDD901

P010015/S208

Consulta CRT-P Model C4TR01, Syncra CRT-P Model C2TR01

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P980016/S425

EnTrust ICD Models D153ATG, D154ATG, D154VRC; Intrinsic 30 ICD Model 7287; Intrinsic ICD Model 7288; Marquis DR ICD Model 7274; Marquis VR ICD Model 7230; Maximo DR ICD Model 7278; Maximo VR ICD Model 7232; Evera S DR ICD Models DDBC3D1, DDBC3D4; Evera S VR ICD Models DVBC3D1, DVBC3D4; Evera XT DR ICD Models DDBB1D1, DDBB1D4; Evera XT VR ICD Models DVBB1D1, DVBB1D4; Marquis II ICD Models D264DRM, D264VRM, D284DRG, D284VRC; Protecta ICD Models D334DRG, D334DRM, D334VRG, D334VRM; Protecta XT ICD Models D314DRG, D314DRM, D314VRG, D314VRM; Secura ICD Models D204DRM, D204VRM, D224DRG, D224VRC; Virtuoso II DR/VR ICD Models D274DRG, D274VRC

P090013/S107

Revo MRI Model RVDR01

Filed: July 8, 2013

Procode: LWS, NIK, NVZ, NKE, OSR

Dear Ms. Johannson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your premarket approval application (PMA) supplement, which requested approval for the MyCareLink Patient Monitor Models 24950 (software version R50), 24951 (software version R50.A.1), and 24955 (software version V29) to be used with the above referenced devices. Based upon the information submitted, the PMA supplement is approved. You may begin commercial distribution of the device as modified by your PMA supplement in accordance with the conditions described below.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Continued approval of this PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. Two copies of this report, identified as "Annual Report" (please use this title even if the specified interval is more frequent than one year) and bearing the applicable PMA reference number, should be submitted to the address below. The Annual

Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

In addition, because your device is a pacemaker, implantable cardioverter-defibrillator (ICD), or system lead, FDA has determined that the following additional information is necessary to provide continued reasonable assurance of the safety and effectiveness of the device. In the Annual Report, provide the following information known by or reported to the applicant:

1. The number of pulse generators domestically implanted and the number of reported explants and deaths.
2. A breakdown of the reported deaths into pulse generators related and non-pulse generator related.
3. A breakdown of the reported explants into the number reported that were:
  - a. For pacemakers and pulse generators: at end of battery life, the number that had complications not resolvable by programming, and, as applicable, the numbers that experienced other safety and effectiveness complications as ascertained by the user, applicant, or otherwise, or
  - b. For leads: associated with mechanical failure, associated with clinical complications, and as applicable, the numbers that experienced other safety and effectiveness complications as ascertained by the user, applicant, or otherwise.
4. The number of pulse generators returned to the applicant for cause from domestic sources, with a breakdown into:
  - a. For pacemakers and pulse generators: the number currently in analysis, the number operating properly, and the number at normal battery depletion and failed (with the failure mechanisms described).
  - b. For leads: the number currently in analysis, the number operating properly, the number failed (with failure mechanisms described); broken down into groupings for full leads and partial leads.
5. A cumulative survival table for the pulse generators.

Before making any change affecting the safety or effectiveness of the device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39.

All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process"

([www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm)).

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or
2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at [www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm](http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm).

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at [www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm](http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm).

CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. Final printed labeling that is identical to the labeling approved in draft form

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will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
PMA Document Mail Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

If you have questions concerning this approval order, please contact James Lee at (301) 796-6360.

Sincerely yours,

**Owen P. Faris -S**

for Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Devices Evaluation  
Center for Devices and  
Radiological Health