SUMMARY OF:

P890003/S280
Reveal DX ICM Model 9528; Reveal XT ICM Model 9529

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, ADDRL1, ADDRS1, 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

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

MyCareLink Patient Monitor Models 24950, 24951, 24955

Medtronic, Inc.
8200 Coral Sea Street

Moundsview, MN 55112

BACKGROUND/REASON FOR SUPPLEMENT

The 180-day PMA/S (subject file) was submitted by Medtronic Inc. (the company) for requesting the approval of the MyCareLink Patient Monitor Models 24950, 24951, 24955 for the above devices. The PMA/S (the subject file) contains the Telemetry C communication and the software modifications.

MyCareLink Patient Monitor, Models 24950 and 24951, have been designed as the replacements for the current monitors (Medtronic CareLink Monitors such as the Models 2490G, 2490H, and 2490C), it also including the MLink cellular adapter, by merging the functionality in order to simplify the design and improve the user experience.

INDICATIONS FOR USE

NOTE: The company claims, "the indications for use" are unaffected by the purposed changes in this PMA/S.

DEVICE DESCRIPTIONS

MyCareLink is a patient monitor used by patients to remotely transmit implantable device data to the CareLink Network for their clinic to view. Communication with the implanted device (interrogation) is achieved through Radio-Frequency (RF) telemetry. Communication to the CareLink Network is achieved through cellular connectivity, or through an optional analog telephone line connection. The subject file is for the Telemetry C only.

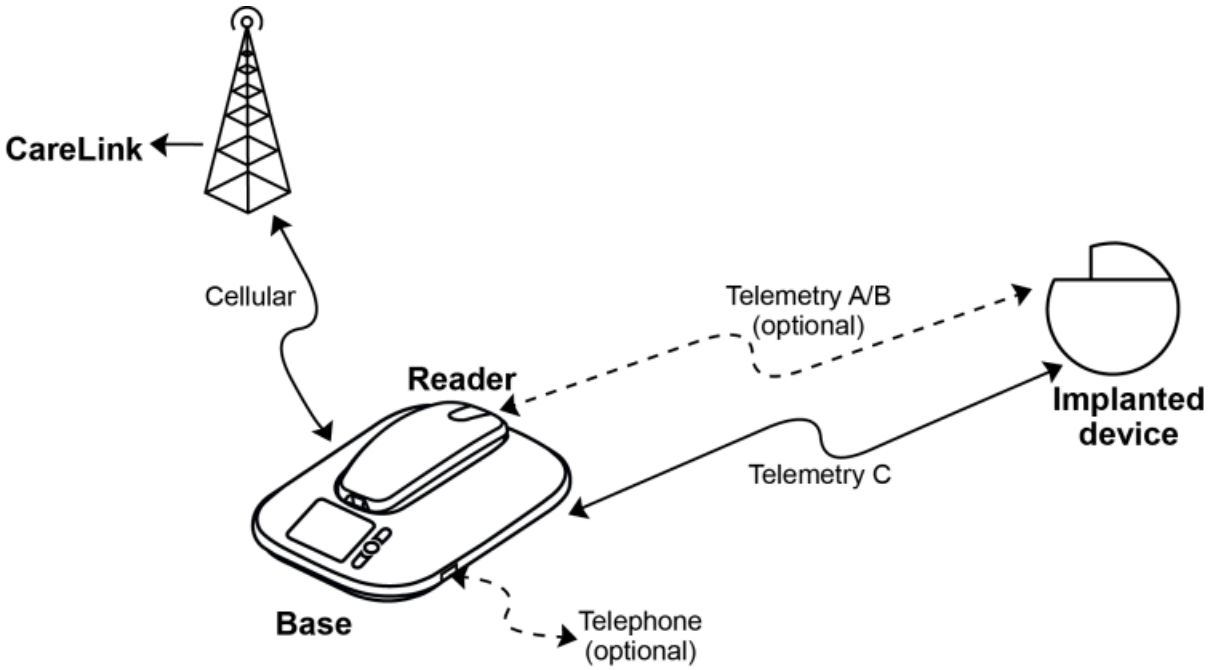
THE SUMMARY FOR THE REVIEW

MyCareLink is a patient monitor used by patients to remotely transmit implantable device data to the CareLink Network for their clinic to view. Communication with the implanted device (interrogation) is achieved through Radio-Frequency (RF) telemetry. Communication to the CareLink Network is achieved through cellular connectivity, or through an optional analog telephone line connection.

The intended use for MyCareLink remains as currently approved for the 2490G/H/C monitors. Although new labeling has been created to reflect the new user experience, contraindications, and relevant warnings and precautions remain the same. MyCareLink is intended for global use, and the labeling has been modified based on the comments from FDA.

MyCareLink was developed and tested in accordance with the Medtronic procedures, and underwent non-clinical bench testing, which included verification testing and system validation testing. Verification testing was conducted on the various subsystems of MyCareLink to establish that the subsystems meet their defined specifications. MyCareLink completed all verification testing. System validation testing was conducted against the overall product requirements specifications, and to assess reliability of the system as it would be used in its intended environment. The reliability of the system was assessed by operating and stressing the system, as it would perform in its intended environment. Typical user scenarios performed during a device interrogation and transmission session were conducted. In addition, the system validation testing stressed the system to assure its specified operation when exercised with unexpected user scenarios. System validation testing also assured operation per its labeling. MyCareLink completed all system validation testing. After FDA reviewed the test reports in the subject PMA/S file, FDA provided the comments to the company, and the company has fully addressed the comments from FDA. Based on the responses from the company, all the testing of the subject device is acceptable.

The follow figure is a general fig. for the system, the subject PMA/S contains the Telemetry C only.



BIOCOMPATIBILITY: N/A

ANIMAL STUDY: N/A

CLINICAL DATA: N/A

LABELING:

The labeling for the subject device is provided in the file, the final drafted version of the labeling in the subject PMA/S is acceptable with the comments from FDA.

CONCLUSION

It is recommended, the approval for the subject file.