SUMMARY OF:

P890003/S269
Reveal DX ICM Model 9528; Reveal XT ICM Model 9529

P010031/S363
InSync III Marquis Model 7279, InSync Marquis Model 7277, InSync Maximo Model 7304, Insync II Protect Model 7295

P980035/S311
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/S190
Consulta CRT-P Model C4TR01

P980016/S400
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

P090013/S085
Revo MRI Model RVDR01

MyCareLink Patient Monitor Models 24950, 24951, 24955

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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 original PMA/S (the subject file) contains the Telemetry A and B only. The company submitted the PMA/S Amendment 01 to include the Telemetry C, and PMA/S Amendment 02 is to withdraw the Telemetry C.

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 SUMMARY FOR THE REVIEW

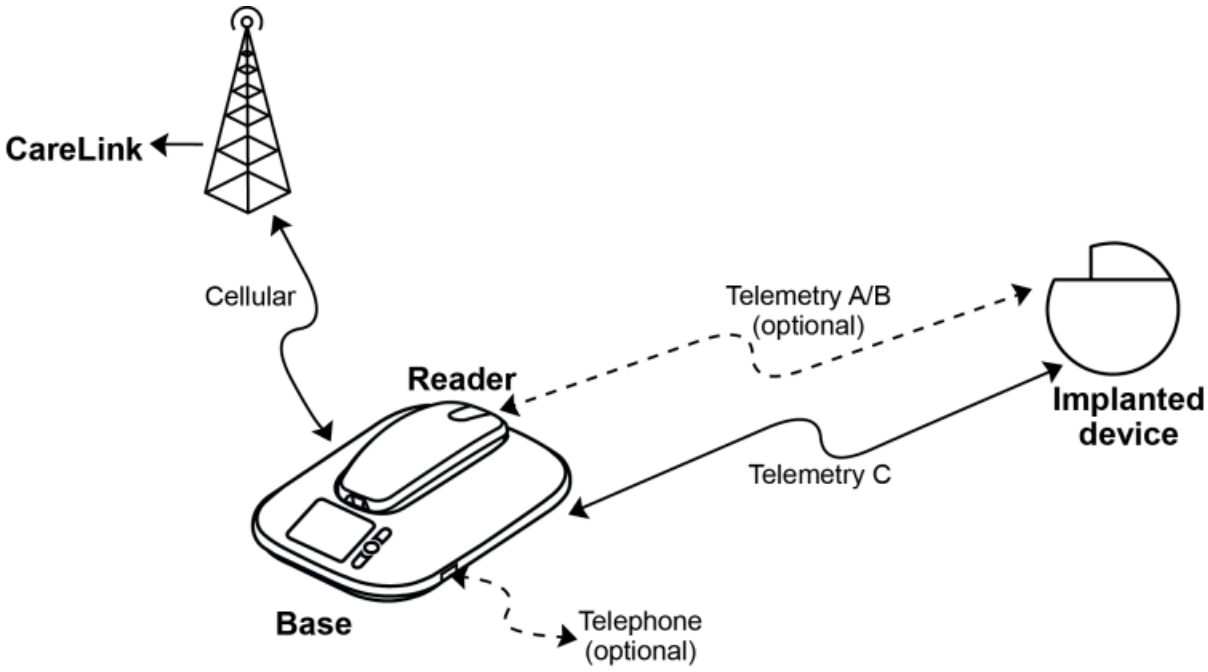
MyCareLink is a patient monitor used by patients to remotely transmit implantable device data to the CareLink Network for their clinic to view. Communication with the implanted device (interrogation) is achieved through Radio-Frequency (RF) telemetry. Communication to the CareLink Network is achieved 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 A, and B only. Telemetry C has been withdrew from the subject PMA/S.



BIOCOMPATIBILITY: N/A

ANIMAL STUDY: N/A

CLINICAL DATA: N/A

LABELING:

The label 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.