SUMMARY OF:

P890003/S254
Reveal

P010031/S319
Concerto II CRT-D, Consulta CRT-D, Maximo II CRT-D, Maximo II DF4, Insync III Protect, Insync II Protect, Concerto

P980035/S280
Kappa 600, Kappa 650, Kappa 700, Kappa 800, Kappa 900, Adapta, Sensia, Relia, Enpulse, Enrhythm, Advisa, Versa, Sigma

P010015/S166
Insync III, Consulta CRT-P, Syncra CRT-P

P990001/S105
Vitatron desktop software application, C60 DR, C20 SR, T60 DR

P980016/S366
Virtuoso II, Maximo II, Secura DF4, Secura, Entrust, Virtuoso

CareLink Encore™ 29901 Programmer 2090 for the above devices

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 CareLink Encore™ 29901 Programmer 2090 for the above devices.

The subject file is a new programmer (system), and this new programmer will contain a new application software package, it was modified from the approved application software packages.

The CareLink Encore™ 29901 Programmer is a modified general purpose computer. Users select desired medical device applications by means of a graphical user interface (GUI) desktop. Communication with the implanted

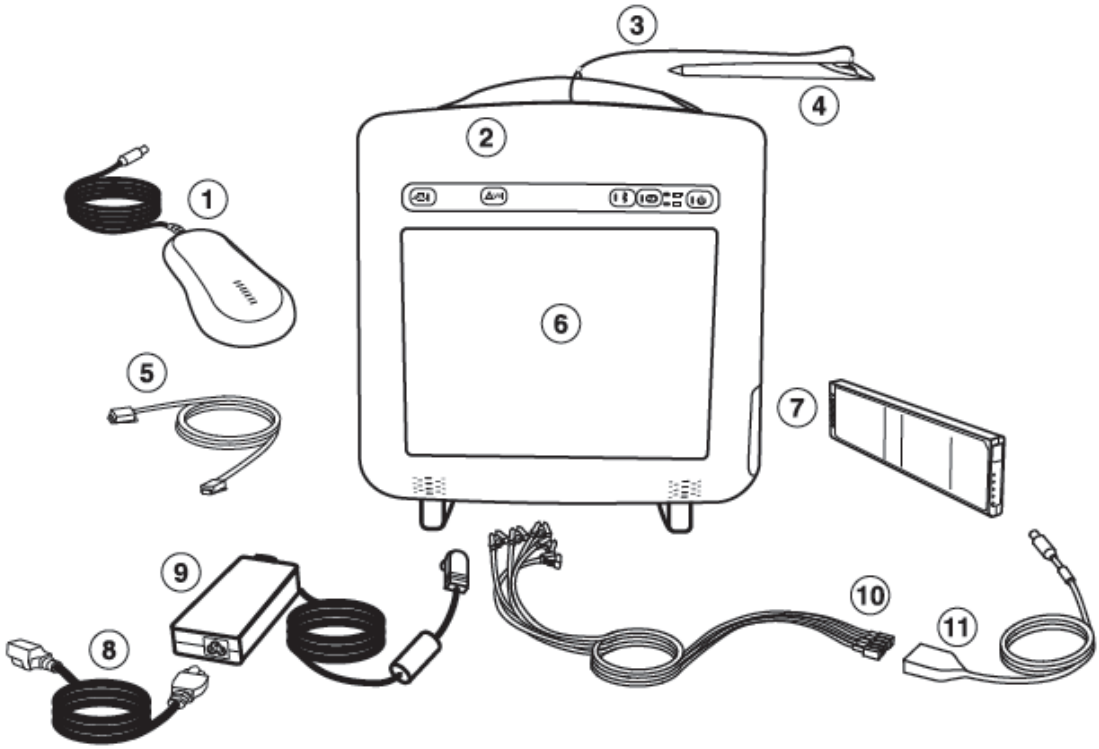
device (interrogation and programming) is achieved through Radio-Frequency (RF) telemetry.

INDICATIONS FOR USE

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

DEVICE DESCRIPTIONS

The CareLink Encore™ 29901 Programmer (also referred to as Encore™ or Encore ™ Programmer) along with its accessories is a cardiac implantable device Programmer System. Figure 1 below shows the Encore™ Programmer and its accessories.



1 Programming head
2 Button panel
3 Tether
4 Stylus
5 Ethernet cable (not supplied)
6 Display screen
7 Battery
8 Power cord
9 Power supply
10 Electrode leads (not supplied)
11 ECG cable with plug (not supplied)

The following accessories of the Encore™ Programmer are provided as part of the product packaging:

 CareLink Encore™ 26901 Programming Head: The CareLink Encore™ 26901 Programming Head (hereafter referred to as the Encore™ Programming Head or simply the programming head) provides the communication link between the

programmer and the patient's implantable device. The programming head contains a strong permanent magnet, radio-frequency (RF) transmitter and receiver, and light array. It must be held over the implantable device during a program or interrogate operation.

NOTE:
The subject item does not work with Telemetry C, it works with Telemetry B only.

 CareLink Encore™ 26905 Stylus and Tether: The CareLink Encore™ 26905 Stylus and Tether (hereafter referred to as the tethered stylus) is used to select options on the Encore™ display screen. Predetermined options are selected by applying the stylus to the screen.

 CareLink Encore™ 26907 Power Supply: The CareLink Encore™ 26907 Power Supply (hereafter referred to as the power supply) when connected to an AC power outlet, enables line-powered operation of Encore™

 CareLink Encore™ 26906 Power Cord: The CareLink Encore™ 26906 Power Cord (hereafter referred to as the power cord) connects the power supply to an AC power outlet.

 CareLink Encore™ 26902 Battery: The battery is a standard general purpose computer accessory that enables portable operation of the Encore™ Programmer.

Notes:

The subject device (programmer system) does not contain the integrated features. This includes the Integrated Pacing Analyzer System and Integrated Chart Recorder.

The printer interface is based on the USB connection, may or may not be supported, pending on the printer models.

The subject device does not contain the Model 2090EC/ECL ECG cable and lead wires.

The subject device does not contain the Ethernet cable.

THE SUMMARY FOR THE REVIEW

The subject device is required to have the system testing, hardware testing, software testing, firmware testing, and environmental testing. In addition, the manufacture and QSR are required to be review by CDRH/OC. Furthermore, the labeling, and other PMA/S related information are required to be reviewed.

(b) (4)

(b) (4)

(b) (4)

(b) (4)

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 PMA/S Amendment 4 is acceptable.

CONCLUSION

It is recommended to send the 'approval' letter to the company.