DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Division of Cardiovascular Devices
Pacing, Defibrillator & Leads Branch

DATE: April 14, 2011

TO: The Record

THRU:
Chief, PDLB/DCD/ODE/CDRH

Initials Date

FROM:

SUBJECT: P950037/S89, P050023/S39, P000009/S42, and P070008/S19
Renamic Programmer and software version PSW 1003.U (original PMA/S)

The PMA/S Amendments (A01 and A02), SW modified, software version PSW 1004.U

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BACKGROUND/REASON FOR SUPPLEMENT

The subject 180 day PMA/S (subject file) was submitted by Biotronik (the company) dated October 27, 2010, requesting approval for Biotronik's new Renamic Programmer with the application software version PSW 1003.U.

FDA issued the letter dated February 4, 2011, and the company submitted the PMA/S Amendment 01 (dated March 10, 2011) to address the deficiencies in the FDA letter. In addition, the application software version has been upgraded to PSW 1004.U.

The company addressed all the deficiencies in the FDA letter in the PMA/S Amendment 01 correctly and acceptable. However, the company omitted the final test report for the

upgraded software version PSW 1004.U under Renamic Programmer environment in the PMA/S A01.

> NOTE: PSW 1004.U, contains additional software fixes, add another implantable device family, and resolved the FDA deficiencies in the PSW 1003.U.

Few e-mails and phone calls were conducted to request the final test report for the software version PSW 1004.U under Renamic Programmer environment. The company submitted the PMA/S Amendment 02 (dated April 8, 2011) for the test report, SW version PSW 1004.U under Renamic Programmer environment. In addition, confirmed all the IDE features and the 'future' features were removed from the subject files.

INDICATIONS FOR USE

NOTE: The "indications for use" are unaffected by the purposed changes in this PMA/S, and are as follows:

For Pacemakers:

Rate-adaptive pacing with BIOTRONIK pulse generators is indicated for patients exhibiting chronotropic incompetence and who would benefit from increased pacing rates concurrent with physical activity. Generally accepted indications for long-term cardiac pacing include, but are not limited to: sick sinus syndrome (i.e. bradycardia-tachycardia syndrome, sinus arrest, sinus bradycardia), sino-atrial (SA) block, second- and third- degree AV block, and carotid sinus syndrome. Patients who demonstrate hemodynamic benefit through maintenance of AV synchrony should be considered for one of the dual chamber or atrial pacing modes. Dual chamber modes are specifically indicated for treatment of conduction disorders that require both restoration of rate and AV synchrony such as AV nodal disease, diminished cardiac output or congestive heart failure associated with conduction disturbances, and tachyarrhythmias that are suppressed by chronic pacing.

For ICDs:

Indications for Use: BIOTRONIK's Implantable Cardioverter Defibrillators (ICDs) are intended to provide ventricular antitachycardia pacing and ventricular defibrillation, for automated treatment of life-threatening ventricular arrhythmias.

For CRT-Ds:
Indications for Use: BIOTRONIK's CRT-Ds are indicated for use in patients with all of the following conditions:

- Indicated for ICD therapy
- Receiving optimized and stable Congestive Heart Failure (CHF) drug therapy

□ Symptomatic CHF (NYHA Class III/IV and LVEF □ 35%)
□ Intraventricular conduction delay (QRS duration □ 130 ms)

Device Description With the Changes:

Hardware Changes:

The following hardware changes with respect to the market approved programmer (ICS 3000 Implant Control System). With the changes, it will be distributed with the trade name "Renamic." Those changes are:

1. Device Case–

A new case design was implemented that allows the device to fold into a more protected carrying case. The Renamic programmer case design includes a compartment for the PGH head and a compartment for the power cord as well as a magnetic slot for the pen/stylus.

2. Printed Circuit Boards –

The company claims that, while the majority of the components on the PC boards are very similar to those of the currently approved ICS 3000 programmer, approved through PMA Supplement P950037/S35 on May 18, 2005, several of the boards have been reconfigured to fit into the modified shape of the Renamic case, such as PCB (b) (4). Other PCBs like (b) (4), (b) (4) and (b) (4) were modified to fit in the Renamic case and to improve the shielding. Additional adapter boards were added to connect these PCBs; however, the functions of all the PCBs remain identical to the functions of the PCBs in the ICS 3000 programmer. In addition, a new PC board ((b) (4)) was added to the Renamic programmer to support the wireless wand module component to be implemented in the future through a separate PMA Supplement. With the exception of the size re-configurations and improved shielding, all other PC boards maintain similar functionality to those of the ICS 3000 programmer.

3. Printer –

A modular printer with improved printing capabilities that slides directly into a slot on the left side of the Renamic programmer.

4. Pen –

The pen/stylus for the touch screen was modified to fit in the compartment designed with the new case. The pen/stylus has a soft and hard tip and is magnetic to stay in the compartmental slot designed to hold the pen/stylus in

place. The modified pen is made from a metal stick (for the magnetic properties), (b) (4) and from (b) (4).

5. PGH Heads –

The programming heads for communicating with pacemakers and ICDs were modified by changing the outer design color, internal air/creepage distances and coding of the Redel plug connector. The Renamic PGH is a programming head with a permanent magnet and the Renamic PGH ICD is a programming head without a permanent magnet. There were no other changes to the PGH heads and the functionality remains the same as the similar two PGH heads used with the currently approved ICS 3000 programmer. The modifications to the programming heads were implemented in order to comply with the revised EN 60601 1 2:2007 standard, 3rd Edition.

6. CD-ROM Drive –

The Renamic programmer will no longer have a CD-ROM drive. The CD-ROM drive was removed and replaced with 2 additional USB ports. Thus, the Renamic programmer will have a total of 4 USB ports (3 external ports and 1 inside the PGH compartment for the Bluetooth USB adapter; whereas, the ICS 3000 programmer has only 2 USB ports. However, with this PMA Supplement, BIOTRONIK will introduce the ability to update Renamic and ICS 3000 programmer software via the USB ports. The ICS 3000 programmer software may continue to be updated via the CD-ROM drive.

7. VGA Port –

A separate VGA port will not be available on the Renamic programmer as it is on the ICS 3000 programmer. However, this functionality is available on the Renamic programmer with a USB port.

8. Battery Power Source –

Unlike the ICS 3000 programmer, the Renamic will only be powered by the mains power cord with AC voltage per the following:

100 – 115 V ±10% / 60 Hz / 1.2 A / AC
220 – 230 V ±10% / 50 Hz / 0.6 A / AC

The Renamic will not have a rechargeable battery power source. Therefore, the Renamic programmer will not have a battery status indicator button or feature in the user interface of the software.

9. Modular Features –

In addition to the hardware changes noted above, three additional changes were implemented in the Renamic to support modular features that will be implemented in the future through separate PMA Supplements. The modular features include the following:

1. Connectivity: The connectivity module will be a Wi-Fi or cell phone modem that can be inserted into a slot in the Renamic programmer. The new hardware required to support this module, a SIM Card slot (on circuit board (b) (4) (b) (4) and two antennas (a (b) (4) and a (b) (4) Antenna), are included in the Renamic programmer.

2. Wireless Wand: The wireless wand module will allow for RF Telemetry programming without any connective wires. New hardware, which includes the PCB (b) (4) and two new (b) (4) antennas, required to support wireless wand capability have been implemented in the Renamic programmer.

3. PSA: A Pacing System Analyzer (PSA) module with similar functions as the currently approved ICS 3000 Implant Module, (P950037/S43, approved on April 24, 2006) will be implemented through a future PMA Supplement.

The Renamic was designed with an open slot to support the PSA module. Although the hardware for the Renamic devices was updated to allow for the modifications listed above, the functions of the device and the indications for use remain the same. The three features listed above cannot be implemented without further changes; therefore these features will not be made available until FDA has reviewed and approved a separate corresponding PMA Supplement or supplements.

NOTE: ODE Reviewer: Those above three features were removed in sw version PSW 1004.U.(PMA/S Amendment 02)

Software changes:

The changes to be implemented with this new programmer software version PSW 1003.U include the following:

_ New GUI design that uses a new screen layout, new boot screen, new start screen and a new implant list design in order to implement the new look and feel of the GUI. The new design will use a white background color scheme, whereas the previous software version used a blue background color scheme. This change will also implement graphical images in the GUI at start up and a change in the order of the navigation and tab screens. The navigator will navigate the user to the following screens in the following order:

_ Follow-up
_ Parameters
_ Tests

_ Episodes
_ Diagnostics
_ Status
_ More
_ Settings
_ Close Session

The GUI design was modified according to customer requests and contemporary software design rules in order to improve usability of the interface. The new order of the navigation and tab screens is designed to be more intuitive for the user during implant follow-up.

_ Software updates via a USB Memory Stick. The new software will offer this feature in addition to the software updates currently performed via the CD-ROM drive. The software will verify the installation files on the memory stick to insure that only original BIOTRONIK files are used for updates. The electronic manual will also be installed or updated via a USB Memory Stick.

_ Improved data export features via USB ports will be implemented.

_ Connection to external hardware (i.e., USB stick) was improved. Previously, if external hardware was connected while the ICS 3000 programmer was running, the user would have to go to the settings window and select “activate new hardware” in order to use it. With this software version, the device will recognize when an external VGA Compatible Monitor is connected and automatically perform these steps so that the external hardware can be used. For all other external hardware that may be connected to the programmer, a new button [Restart system] that initiates a reboot of the system has been added. This new button will make use of external hardware devices easier and faster for the user.

_ New print job categories that will be capable of printing out a single page summary of guided followup. A new print job category named “Summary of follow-up” was added which prints out a single page summary of test results after interrogation, even if manual test has been performed. In order to avoid confusion with the existing print job category “Summary of follow-up,” this category was renamed to“ Summary of guided follow-up” in this version of the programmer software. The user can still set their preferred settings and naming conventions for printing reports in the “Preferences/Print” screen.

_ Automatic identification of programmer devices as US programmers by checking the current version of software. The new software will then define the ICS 3000 programmer device as a US programmer for future software upgrades.

_ Standard setting for the ECG/IEGM display of the threshold test will be changed from ECG to IEGM. Since a majority of the users switch from ECG to IEGM, it is more helpful to have the IEGM as a standard setting. This change affects only the Evia and Lumax devices.

_ Recognition of hardware dependent features was incorporated into this version of the software, in order to make the software compatible with both versions of hardware (Renamic and ICS 3000). The availability of the following features is hardware dependent:

I) Button to activate/deactivate the esophagus ECG channel: The Renamic programmer will no longer support this feature; however, the ICS 3000 programmer will continue to support the esophagus features.

a. All GUI controls related to existence of a battery: Since the Renamic programmer is not battery powered, this device will not need to support GUI controls for interacting with the battery. Meanwhile, the ICS 3000 programmer will continue to support these features.

II) Linking of interrogated implant with CardioMessenger through infrared interface: The Renamic programmer will no longer support this feature; however, the ICS 3000 programmer will continue to support the linking with CardioMessenger.

III) Printer: The Renamic programmer will have a new printer supplied by a new supplier and the software version will need to recognize the differences in the printer between the Renamic and the ICS 3000 programmers.

IV) CD drive: Since the Renamic programmer does not have a built-in CD drive, the options to export follow-up data to a CD-RW target are not applicable and the CD drive is not shown in the export status dialog.

V) Export to CDM connected through serial interface: The Renamic programmer does not have a serial interface; however, a USB-to-serial adapter is supported in order to connect a CDM through a serial line and export follow-up data.

VI) Display of serial numbers for operation module and docking unit under on programmer screen: The Renamic programmer is a one-piece device and only has one serial number. The ICS 3000 programmer will continue to display separate serial numbers for the operating module and the docking station.

VII) **PSA (Implant module) extension unit: A PSA module for the Renamic programmer is not yet available**. However, the ICS 3000 programmer will continue to support the Implant Module extension unit including the corresponding programmer application. ***(ODE Reviewer: This is removed in the sw version, PSW 1004.U.)***

In addition to the changes listed above, the following bug fix was incorporated into the new programmer software version PSW 1003.U:

_ Previously, there was the possibility that programmer may enter an unspecified state after exporting follow-up data through the RS-232 interface,

this was corrected. This bug fix only affects the ICS 3000 programmer, since the Renamic programmer does not have a RS-232 interface.

NOTE: ODE Reviewer: all the features that is associated to IDE should be removed from this PMA file, and it is removed in the software version, PSW 1004.U .)

Packaging Changes

The package changes of this new programmer is stated under the hardware change section.

REVIEW TEAM

OSEL Software review for the original PMA/S.

PRECLINICAL/BENCH

BIOCOMPATIBILITY/MATERIALS: N/A

ANIMAL STUDIES: N/A

HARDWARE/SOFTWARE: TESTING:

The composition process performed sub-system verification tests for all components, including the hardware and software. Additionally, for each increment, system level tests have been performed to demonstrate that the increment's goals have been accomplished and that the components are compatible with each other (system integration testing). After final system integration, system verification was performed to demonstrate that all system requirements have been fulfilled. The testing was carried out according to verification test plans for the Renamic System, ICS-Neo Standards, ICS-NEO software system, ICS-Neo Subsystem, ICS-NEO hardware subsystem, software system and the software subsystem, respectively. All verification test plans for the Renamic programmer and the software application PSW 1003.U have been successfully completed as summarized in Table 8 and Table 9 of the submittal.

The existed software anomalies in the PSW 1003.U and 1004.U:

Particular screen navigation sequences (e.g. Freeze Window scrolling, data manager scroll bar movement) may cause IEGM/ECG display judder resulting in incorrectly short time intervals.

This is display problem, the company claiming it is low risk. The ODE Reviewer agree it based on the 'newly' enhanced re-start feature in this subject programmer.

The user may be unaware of an existing preprogramming of an implant in shelf mode since interrogation doesn't provide an explicit indication. Particularly, the fixed pace polarity after preprogramming may be neglected and confused with auto pace polarity present in regular shelf mode.

(b) (5)

Minor usability issue: Missing ECG scaling function when performing a manual threshold test and ECG is selected, as for other diagnostic tests. ECG re-scaling requires stopping the test, navigating to Parameter Screen, adjusting the scaling, re-navigating to tests and starting the threshold test again. This is more time consuming.

This is display problem, the company claiming it is low risk. The ODE Reviewer agrees with the company.

Minor usability issue: Suboptimal color scheme resulting in difficulties to discern the yellow dotted trigger line in the test window.

This is display problem, the company claiming it is low risk. The ODE Reviewer agrees with the company

Usability issue: Layout of Manual Threshold Test Screen does not provide sufficient space for ECG display covering the lower half of the ECG channel.

This is display problem, the company claiming it is low risk. The ODE Reviewer agrees with the company

Minor parameter printout issue: For nonrate adaptive mode (e.g. VVI) for the parameters "Sensor/Rate fading " instead of "-----/OFF" as displayed on screen "/OFF" is printed.

This is display/printing problem, the company claiming it is low risk. The ODE Reviewer agrees with the company

Follow-Up history records may be overwritten unexpectedly by a new follow-up record during interrogation from implant list when lead failures are present.

This is software problem, the company claiming it is medium risk. The ODE Reviewer agrees with the company

Battery status "ERI" incorrectly displayed for particular scenario. If implant is in shelf mode and is interrogated, implanted and Automatic Implant Detection function has started but not completed, and afterwards the implant is interrogated within the same follow-up session (programmer application not

left to implant list) in the screen Follow-up history incorrectly the battery status "ERI" is shown and printed. After AID completion and termination and/or subsequent interrogation from implant list the battery status in the follow-up history is correctly displayed as "100%". Fuel gauge and battery status in parameter screen and printout are always correct.

This is software problem, the company claiming it is medium risk. The ODE Reviewer agrees with the company

A new EMC report according to the EN-60601-1-2 Standard was compiled by an independent testing laboratory, (b) (4), to verify that the modifications to the Renamic are within the EMC requirements. The Renamic EMC Test Report and results were provided in the submittal. Renamic PGH EMC Test Report and results were provided in the submittal.

Additionally, the Renamic was tested by an independent CB testing laboratory, (b) (4) (b) (4), to verify compliance with IEC 60601-1: Medical electrical equipment, Part 1: General requirements for basic safety and essential performance, 3rd Edition. The results of the testing indicated that the Renamic programmer is in accordance with the current standard. The CB Test Report, Certificate and results were provided in the submittal.

Based on the above listed test reports, the tests are passed, therefore, it is acceptable.

The summary of the review for the PSW 1004.U (PMA/S Amendment 01):

PSW 1004.U application software for Renamic programmer contains the application software for Estella and Effecta pacemakers, the remove of the future and the IDE features, and the fixing of the following software anomalies:

Bug fix to avoid unexpected data export for sensing test results when an intrinsic rhythm test is performed after a P/R wave measurement test. Currently, the most recent (b) (4) instead of (b) (4) (b) (4) from the Sensing Test.

Improve the accuracy of Time to ERI predication through an (b) (4) (b) (4) .

Bug fix for marker annotations which are missing on the Freeze and Recording prints for certain color schemes.

Bug fix for Scrolling in the Freeze window, which can create extra markers in the real time marker channel.

Bug fix for statistics unavailable after device interrogation when Thoracic Impedance feature is enabled for Home Monitoring, but deactivated in the programmer application. (This was an extremely rare potential event.)

Bug fix for a software reset of the internal circuit board (PCB (b) (4)) after incorrect enumeration (boot-up process). Currently, the following error can occur in Renamic programmers used at high temperatures (stress testing at (b) (4) °C): When the device is turned OFF and then immediately turned back ON, an unwarranted error message may appear. This error is corrected after the Renamic programmer is turned OFF and the ON again. With this software bug fix, the Renamic error will no longer occur.

The PMA/S Amendments 01 and 02 addressed the following deficiencies:

Deficiency 1 – SOFTWARE DESCRIPTION

You did not provide a complete Software Description. Please provide a comprehensive overview of the device features that are controlled by software, and a description of the intended operational environment. This should include information on the programming language, the hardware platform, the operating system (if applicable) and the use of Off-the- Shelf software (if applicable).

The company response: *An overview of the features and software operating environment for 1004.U is summarized in the System Requirements Specification document PFH-461-022 document and provided in the submittal (PMA/S A01).*

Review*: Based on the information in the file, it is acceptable.*

Deficiency 2 – ARCHITECTURE DESIGN CHART

You did not provide an Architecture Design Chart. Please provide a detailed depiction of functional units and software modules, which may include state diagrams as well as flow charts.

The company response: *The high level software architecture design document which includes a detailed depiction of the functional units and software modules is summarized n SAD-469-004 and provided in the submittal (PMA/S A01).*

Review*: Based on the information in the file, it is acceptable.*

Deficiency 3 – SOFTWARE DESIGN SPECIFIACTION

You did not provide a Software Design Specification. Please provide a Software Design Specification document, which describes how the requirements in the Software Requirements Specifications (SRS) are implemented. The information presented in the SDS should be sufficient to ensure that the work performed by the software engineers who created the software device was clear and unambiguous, with minimal ad hoc design decisions. The document that you submit should provide adequate information to allow for the review of the implementation plan for the software requirements in terms of intended use, functionality, safety and effectiveness. These should be presented in an enumerated manner, referencing the associated Software requirements.

> ***The company response:*** *The software design specifications are summarized the company's software detailed design documents. As an example of this type of document, SDD-115-039 is provided in submittal (PMA/S/A01). In addition, VER-10-1140 is a design review assessment in a test report format which lists all of the SDD documents that were used in the development of SW 1004.U is provided in the submittal (PMA/S/A01) This test checks the current software system design for 1004.U against the previous software system design to identify any design changes. System parts with changed design are tested in dedicated tests during system verification. System parts with unchanged design are identified and checked for appropriate and successful sub-system test coverage.*
>
> ***Review****: Based on the information in the file, it is acceptable.*

Deficiency 4 – SOFTWARE DEVELOPMENT ENVIRONMENT

You did not provide a description of the Software Development Environment. Please provide a description of the software development environment, which should include a Summary of the software life cycle development plan, and an annotated list of the control documents generated during the development process. Please include the configuration management and maintenance plan documents.

> ***The company response:*** *The software development process is summarized below, and is accomplished in accordance with the following BIOTRONIK internal documents:* ***GPA-111-049: Business Process Guideline - Development of Medical Device Software.*** *For all software verification and validation testing, adherence to the company's standard operating procedure GPA-111-049 is required.*
>
> *The validation and verification tests are according to two types of test plans. The verification summary report (VEB) demonstrates that the requirements have been fulfilled. The validation plan (VPL) demonstrates that the user requirements have been met. Both test plans share the same test report format (VER). Specifically for the 1004.U programmer software version, the*

following testing activities were performed during the development at all integration levels:

- *Unit Tests according to unit test summary SWV-469-006 Primus MidEco Programmer;*
- *Software Requirement Verification according to subsystem verification test plan VEB- 469-0003;*
- *System Requirement Verification according to system verification test plan VEB-111-0497 Primus MidEco System Verification;*
- *Primus MidEco Programmer Validation according to validation plan VPL-111-1462;*
- *Primus MidEco Implant validation according to validation plan VPL-111-1395;and*
- *Programmer Software SW 1004.U (Field Release for all products) validation according to validation plan VPL-111-1684.*

Project specific information is contained in a SDP document. For 1004.U the programmer software development plan was SDP-469-006. A review of the following standards is conducted to ensure compliance with pertinent development process requirements for medical product software:

- *Test protocol compliance with standard IEC 60601-1-4 (Development of PEMS): Check List IEC 60601-1-4 Primus MidEco;*
- *Test Report compliance with standard IEC 62304: VER-111-10-2836.*

***Review**: Based on the information in the file, it is acceptable.*

Deficiency 5 – REVISION LEVEL HISTORY

You did not provide a Revision Level History. Please provide a revision history log, which provides the history of software revisions generated during the course of product development. Note: This is typically a line-item tabulation of the major changes to the software during the development cycle, including date, version number and a brief description of the changes in the version relative to the previous version. The last entry in the list should be the final version to be incorporated in the released device. This entry should also include any differences between the tested version of software and the released version, along with an assessment of the potential effect of the differences on the safety and effectiveness of the device.

The company response: *The revision level history of PSW 1004.U is provided below:*

- *Test Release History SW 1004.A: VER-111-10-2756 (Development of CE version of Primus MidEco Programmer.)*

- *Test Release History SW 1004.U: VER-111-10-3415 (US configuration of SW 1004.A)*

Review*: Based on the information in the file, it is acceptable.*

Deficiency 6 – CYBERSECURITY

You did not provide information on Cybersecurity. Please provide information, as appropriate, on the Cybersecurity aspects of your device, including, but not limited to, the following facets of information security with respect to communications features of your device and associated software: Confidentiality, integrity, availability and accountability. Confidentiality assures that no unauthorized users have access to the information. Integrity is the assurance that the information is correct - that is, it has not been improperly modified. Availability suggests that the information will be available when needed. Accountability is the application of identification and authentication to assure that the prescribed access process is being done by an authorized user

The company response: *The Renamic/ICS 3000 programming system is not a Networked Medical Device in the sense of FDA's Cybersecurity Guidance. While the programmer's software contains Off-the-Shelf Software (Windows XP embedded) it cannot be directly connected to a private intranet, public internet, or other network. Data interfaces supported by the programming system (e.g. USB, CD-ROM drive, Bluetooth, coil telemetry) only allow connections to media and peripheral devices. These interfaces are strictly under the subject company's control and are appropriately covered by risk control measures required by the corresponding risk analysis. (*The company listed out the examples of those Risk Control Measures, and provided the explanations.)

Review*: Based on the information in the file, it is acceptable.*

Deficiency 7 – MODULAR FEATURES

As you have stated in page 34, Section 5.9 Modular Features, all three features will be modified in the future, and additional PMA/Ss will be submitted for review in the future. In addition, it appears the Pacing System Analyzer (PSA) is not ready for the Renamic programmer at the present time. Therefore, please provide the information which demonstrates the safety and effectiveness of those

three features in the subject file, otherwise, please remove it until you are able to do so in the future. Those are: The Wi·Fi connectivity modular; Wireless wand modular; and the PSA modular.

The company response: *Those features were removed in the software of Renamic programmer.*

Review*: Based on the information in the file, it is acceptable.*

Deficiency 8 – TIM SOFTWARE CHANGE

As you have stated in page 40, Section 6.4 Software Changes Affecting Tachy Applications, the software fix for the IDE feature shall be reviewed under the IDE process, not under the PMA review process. In this case, the IDE feature is Thoracic Impedance Measurement (TIM), and this feature is for the IDE only. With above, please remove this feature from the subject PMA file, and submit the IDE software fix under the 21 CFR Section 812.

The company response: *The feature was removed in the software of Renamic programmer.*

Review*: Based on the information in the file, it is acceptable.*

Final Deficiency: TEST REPORT FOR THE PSW 1004.U:

You have omitted the submission of the final test report for the SW version PSW 1004 with the Renamic programmer, please the test report for review. In addition, the test report should include the new additions (modifications) to the software package, and the regression tests.

The company response: *The test report is submitted as the PMA/S A02.*

Review*: Based on the information in the file, it is acceptable.*

CLINICAL DATA: **N/A**

CONCLUSION

Based on the information in the file, the company has provided appropriate data to demonstrate this new programmer with the PSW 1004.U is acceptable.

RECOMMENDATION – Approval.

[redacted] **Date**

Reviewer

[redacted] **Date**

Chief, PDLB