
**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: September 22, 2011
TO: The Record
THRU: [REDACTED]
Chief, PDLB/DCD/ODE/CDRH

Initials	Date
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FROM: [REDACTED]
SUBJECT: P070008/S26, P950037/S98, P050023/S46, P000009/S46
Renamic Programmer and software version PSW 1101.U
CONTACT: Jon Brumbaugh
Vice President, Regulatory Affairs and Compliance
Biotronik, Inc.
6024 Jean Road
Lake Oswego, OR 97035-5369
Tel: [REDACTED]
Fax: [REDACTED]

BACKGROUND/REASON FOR SUPPLEMENT

The subject 180 day PMA/S (subject file) was submitted by Biotronik (the company) dated August 19, 2011, requesting approval for Biotronik's new Renamic Programmer with the application software version PSW 1101.U.

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:

The company provided the description of the Renamic Programmer and the subject application software. In general, the functions of the programmer did not change except the following items (hardware and software).

Hardware Changes:

The company ‘replaced’ the mother board (by, (b) (4) (b) (4)) for the programmer. With above statement, it is reviewer’s point of view that, we are looking at a new programmer. By, (b) (4)

The new board contains (b) (4) (b) (4) Ghz.0 or (b) (4) (b) (4) GHZ.); (b) (4) ; Ethernet; sound and Video, etc.

Software changes:

The software changes for the new programmer, version PSW 1101.U, which includes the following:

Software platform improvements for the Evia family of pacemakers (P950037/S72 approved May 7, 2010 and P950037/S92 approved February 11, 2011),

Support Lumax and Evia Family firmware updates,

Modified default parameters for the Lumax 540 VR-T DX (P050023/S029, approved April 30, 2010), and

Bug fixes for global, brady and tachy applications.

NOTE: based on the detailed description for the software changes above, this version of the application software package contains the firmware updates for the pacemakers (Evia family) and ICDs (Lumax 300/340 and 500/540). Based on the conference call on September 19, 2011, the company confirmed, all the features for the 'will be' download firmware for the pacemaker and ICD were approved by FDA prior this submittal.

PACKAGING CHANGES: N/A

REVIW TEAM: N/A

PRECLINICAL/BENCH

BIOCOMPATIBILITY/MATERIALS: N/A

ANIMAL STUDIES: N/A

HARDWARE TESTING:

The company conducted the following hardware testing:

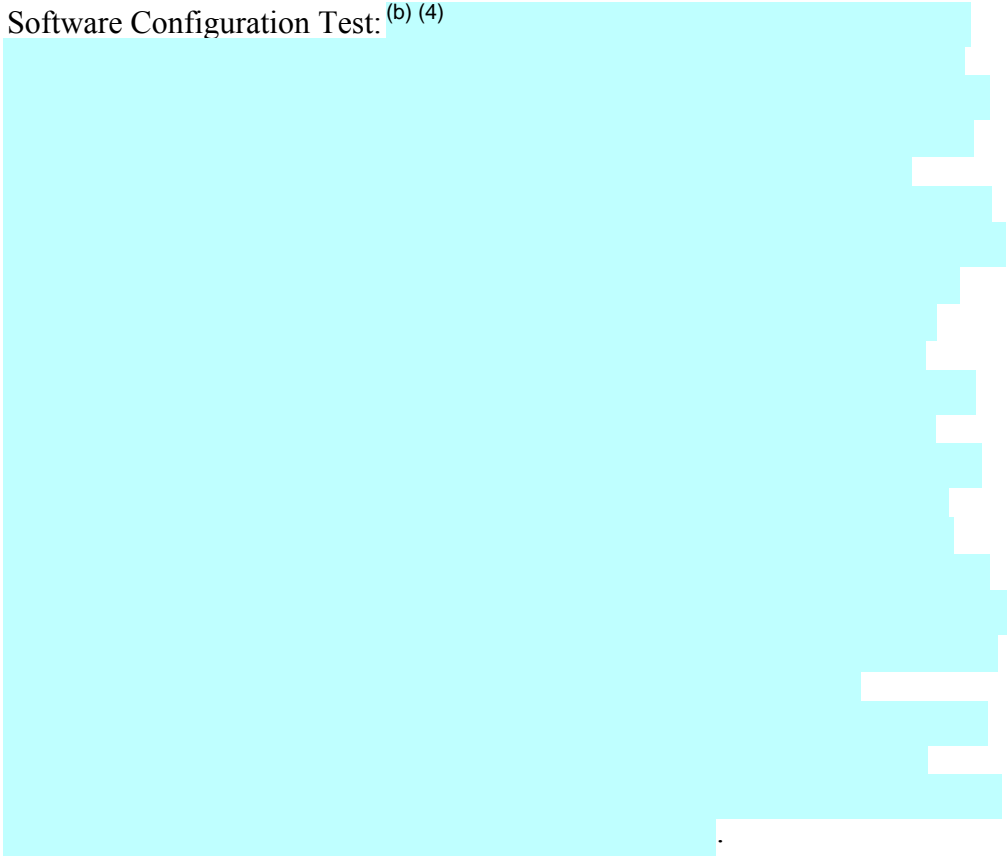
Shipping Configuration, Transport and Storage Environment: Accessories - Shipping Configuration, Transport and Storage; Operation on Limits of Environmental and Mains Power Conditions; Characteristics of the Display; Audible Signaling; Positions and Functions of Keys; Internal Clock; Internal CPU and Storage; Compatibility with Current Programmer Software; Certifications (Technical Safety); Reliability of the Internal Printer; Interfaces; ON/OFF Switch; Printed User Manuals; Completeness of Verification; Factory End Test; Product Identification; Renamic EMC Test Report; CB Test Report and Certificate.

The company claiming, all the above testing are passed. Therefore, this item is acceptable.

SOFTWARE TESTING:

The company conducted the following software testing

Software Configuration Test: (b) (4)



The existed software anomalies: (NEW)

(b) (4)



Display/printout of incorrect diagnostic information may cause user confusion

Justification of Acceptance from the company: Correct impedance values are displayed for next Follow-Up session (after next initial interrogation). Behavior accepted as is due to acceptable residual risk resulting from low severity and low probability of occurrence. Product safety and performance are only marginally affected.

Review: This is acceptable.

248125: (b) (4)

Functional/Usability Issue (missing, insufficient user guidance, unexpected behavior) without clinical relevance or negative therapeutical/diagnostic implication.

Justification of Acceptance from the company: Behavior accepted as is due to low residual risk resulting from very low severity. Product safety and performance are only marginally affected.

Review: This is acceptable.

64794: (b) (4)

Diagnostic Data Issue (Interrogation, Display, Printout): Display/printout of missing diagnostic information may cause user confusion.

Justification of Acceptance from the company: Behavior accepted as is due to acceptable residual risk resulting from low severity and low probability of occurrence. Product safety and performance are only marginally affected.

Review: This is acceptable.

55573: (b) (4)

Functional/Usability Issue (missing, insufficient user guidance, unexpected behavior) without clinical relevance or negative therapeutical/diagnostic implication.

Justification of Acceptance from the company: Behavior accepted as is due to acceptable residual risk resulting from low severity and low probability of occurrence. Product safety and performance are only marginally affected.

Review: This is acceptable.

45259: (b) (4)


Functional/Usability Issue (missing, insufficient user guidance, unexpected behavior): User confusion possible about change status of parameters, with minor clinical relevance or negative therapeutical/diagnostic implication

Justification of Acceptance from the company: Behavior accepted as is due to acceptable residual risk resulting from low severity and low probability of occurrence. Product safety and performance are only marginally affected.

Review: This is acceptable.

The existed software anomalies: (Known/Existed)

19607: (b) (4)

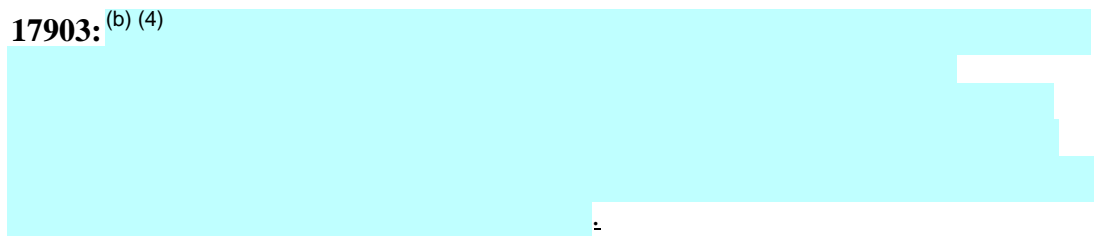


Unexpected/Unspecified behavior with clinical relevance or negative therapeutical/diagnostic implication: Reduced therapy, sudden rate drop if rate was elevated due to activity sensor, post shock pacing rate should be set to 70ppm or higher.

Justification of Acceptance: Therapy is only marginally compromised, no safety concern, temporary situation, low probability.

Review: This existed anomaly was accepted by FDA prior to this file. It is acceptable.

17903: (b) (4)



Unexpected/Unspecified behavior with clinical relevance or negative therapeutical/diagnostic implication: more sub-threshold pace pulses may be delivered than programmed.

Justification of acceptance:

Physician is near the patient when this situation occurs, non-capture is immediately recognizable, lifting the wand immediately reverts to the previous permanent pacing program and capture condition, termination of temporary program by wand lifting is a common feature, probability of occurrence is very low. Accepted due to low probability of occurrence and very low severity.

Review: This existed anomaly was accepted by FDA prior to this file. It is acceptable.

FIRMWARE TESTING:

The company conducted the following firmware testing;

(b) (4)



Note:

The new Evia family firmware version is: 6.05;

The new Lumax 300/340 firmware version is: 5.2.3; and

The new Lumax 500/340 firmware version is 6.0.2.

CLINICAL DATA: N/A

CONCLUSION

Based on the information in the file and the comments from the September 19, 2011 conference call with the company, the company has provided appropriate data to demonstrate this new programmer are acceptable.

RECOMMENDATION – I recommend that this PMA supplement to be **Approve.**

James Lee **Date**
Reviewer

Mitchell Shein **Date**
Chief, PDLB