Premarket Approval [PMA] Review
180-Day Supplement
P950037/S079

Date: March 23, 2010
To: The Record
From: (b) (6)

Office: ODE
Division: DCD

Device Name: Reliaty External Pacemaker Pulse Generator
Model 3145 External Pacemaker Pulse Generator

PMA Holder: Biotronik, Inc.
Lead Reviewer: (b) (6), Biomedical Engineer
Consultants: (b) (6), MD, Clinical

Recommendation: Approve (APPR)

(b) (6) Date

Mitchell Shein Date

I. Purpose and Submission Summary

This 180-day PMA-S is requesting approval for the Reliaty / Model 3145 Pacing System Analyzers. The design represents further development of the previously approved ICS 3000 Implant Module device which was approved under P950037/S043. The name change was introduced to indicate that the new Reliaty/Model 3145 is a stand-alone device. Table 1 shows the device models and accessories.

Table 1: Product Information

	Trade or Proprietary Name	Model Number
1	Reliaty Pacing System Analyzer	(b) (4)
2	Model 3145 Pacing System Analyzer	(b) (4)
3	Model 3150 Cable	(b) (4)
4	Model 6653 Cable	(b) (4)
5	Model 6646 Cable	(b) (4)
6	Model 6652 Adapter	(b) (4)

The firm submitted an amendment to this file on June 3, 2010 which amends the labeling to specify that the device is contraindicated for use outside of the implant procedure.

II. Device Description

Indications for Use: The Reliaty/Model 3145 is indicated for use in pacing lead system analysis during the implantation of pacemakers and defibrillators.

The Reliaty/Model 3145 Pacing System Analyzer (PSA) will be a stand-alone triple chamber pacing system analyzer for use during pacemaker and ICD implantation. The functionality of the device is identical to the PSA options of Biotronik's ICS 3000 module with the exception that the Reliaty/Model 3145 will be a stand-alone device. It also has many features that are similar to Biotronik's ERA 300 and ERA 3000 devices cleared under K022360 and K964190 respectively.

The device will be available in 2 versions: the Reliaty will be marketed by Biotronik and the Model 3145 will be marketed by Boston Scientific. Unless otherwise noted in this memo, both versions will be referred to as Reliaty and the ICS 3000 Implant Module will be referred to as the ICS 3000 or the Implant Module.

Figure 1: Reliaty Stand Alone PSA

The user interface is a touch screen in combination with a turning knob containing a mechanic-optical encoder with wheel, six LED indicators and seven buttons on the front panel. The user controls the operations of the device through its LCD touch-screen,

control-knob and control buttons. The user monitors device measurements, heart activity and device status through its LCD display and LED indicators. The touch screen is identical to the ICS 3000 Implant Module, the turning knob and LED indicators are identical to the interfaces provided in the ERA 3000 and the ERA 300.

The Reliaty provides 3-chamber pacing and sensing. It can display up to 3 channels of real-time IEGMs (intracardiac electrograms) and markers. With the exception of bi-ventricular pacing, the device provides standard PSA functionality identical to the Implant Module with measurements such as lead impedance measurements, intrinsic amplitude, timing measurements and pacing thresholds. These functions are described in Section 4.5 of the submission. It has a report feature that provides a summary of device measurements along with optional IEGM traces. It has a freeze/timing feature that allows the user to snap shot IEGM traces for contrast and to analyze IEGM morphologies. The Reliaty/Model 3145 can also deliver an emergency VVI pacing feature that provides immediate single chamber pacing.

The Reliaty/Model 3145 introduces a new combined power management system and can be powered directly by an external power supply module (FRIWO FW 7555M/08) or alternatively by non-rechargeable batteries. It also uses new input filter characteristics for the Model 3145. The Implant Module uses the same adjustable sensitivity values related to a $\sin^2$-pulse (15 ms pulse width / atrium, 40 ms pulse width / ventricle) as the ERA 300 and ERA 3000 use.

Two connector ports (one for the RA and RV and one for the LV) on the back of the pacing system analyzer allow connection of cables linking the Reliaty/Model 3145 to the lead system for pacing and lead system tests or to the implantable pulse generator for parameter measurements. The cables and adapters are identical to those approved for use with the ICS 3000 Implant Module, ERA 3000 and the ERA 300. The Boston Scientific Model 3145 cables and adapters are mechanically identical to the corresponding BIOTRONIK Reliaty cables and adapters; they are also identically packed and sterilized. Section 4.7 describes the accessories to the systems.

Finally, the technical interface has USB and VGA connections. The device has a VGA output port that can be connected to an external CRT/LCD display. The device also has a standard USB 2.0 (12 MBit/s) connector that can be used to export measurement reports to a USB flash memory stick or print those reports to a Bluetooth printer. Only USB modules that comply with the Microsoft Bluetooth Stack standard can be used. The functions of the USB and VGA connections are identical to those of the currently approved ICS 3000 Implant Control System (P950037/S74).

Accessories

Table 2 shows the various accessories that are included with this system. Most of the accessories are currently being used with the ICS 3000 or ERA 3000 and have been approved through a PMA-S or cleared via 510(k) as listed.

Table 2: Accessories

Accessory	Description	PMA or 510(k)
BIOTRONIK Accessories for Reliaty		
PK-141	Patient cable with alligator forceps, sterile, resterilizable	K083674, dated April 1, 2009
PK-67-S	Patient cable, sterile, resterilizable	K022360, dated January 27, 2003
PK-67-L	Patient cable, sterile, resterilizable	K022360, dated January 27, 2003
PK-155	Patient cables (2) with alligator forceps for single use, sterile	K022360, dated January 27, 2003
PA-1-B	Adapter for 2 mm pins, sterile, resterilizable	K022360, dated January 27, 2003
PA-2	Adapter with IS-1 cavities, sterile, resterilizable	P980023, dated October 27, 1998
PA-4	Adapter with alligator clips, sterile, resterilizable	K022360, dated January 27, 2003, and P980023, dated October 27, 1998
Boston Scientific Accessories for Model 3145		
Model 3150	Patient cable with alligator clips, sterile, resterilizable (identical to PK-141)	Introduction is subject of this submission
Model 6653	Patient cable, sterile, resterilizable (identical to PK-67-S)	Introduction is subject of this submission
Model 6646	Patient cable, sterile, resterilizable (identical to PK-67-L)	Introduction is subject of this submission
PK-155	Patient cables (2) with alligator forceps for single use, sterile	K022360, dated January 27, 2000
Model 6652	Adapter with alligator clips, sterile, resterilizable (identical to PA-4)	Introduction is subject of this submission

III. Description of Changes

Table 3 shows a comparison of clinical features.

Table 3: Clinical Features

Function/Parameter	Dim.	ICS 3000	Reliaty/Model 3145
Atrial: Stimulation Sensing	N/A	 On, Off (via Mode selection)	 On, Off On, Off
Right Ventricular: Stimulation Sensing	N/A	 On, Off (via Mode selection)	 On, Off On, Off
Left Ventricular: Stimulation Sensing	N/A	 On, Off On	 On, Off On, Off
Triggered Stimulation	N/A	(via Mode Selection)	On, Off
LV Pace Polarity		(b) (4)	(b) (4)
VV-delay	ms	(b) (4)	(b) (4)

Bi-Ventricular Pacing

The most clinically significant feature of this device is its ability to function as a bi-ventricular external pacemaker during analysis of lead systems. Since it is a stand-alone device there is the possibility that it might be used as a temporary external pacemaker pulse generator. External pacemaker pulse generators are 510(k) devices but none of the currently marketed models have bi-ventricular pacing capability.

Bi-V pacing is typically part of a CRT system which has different intended use and indications for use than single chamber or dual chamber (RA-RV) pacing. We discussed this issue with Mr. Jon Brumbaugh of Biotronik and he confirmed that this device is only intended to be used as an external pacemaker during lead system analysis. Biotronik subsequently submitted a labeling amendment on June 7, 2010 which updated the User Manual and Technical Manual.

The contraindications listed on page 9 of the User Manual were revised to add:

- *Use as an external pacemaker outside of the implant procedure*

Also page 7 of the Technical Manual added the following item:

Note: During the implant procedure, the Reliaty PSA can temporarily take over the pacing functions of a pacemaker in up to 3 chambers of the heart.

(b) (6) provided a clinical review of this section as well as the amendment document. Her review memo is provided as Attachment 1 to this memo. She had a number of deficiencies that were addressed interactively. Biotronik responded to each deficiency in a July 30, 2010 email (Attachment 2).

(b) (6) and I discussed the responses during a phone call on August 4, 2010. We agree that they are adequate and have no further concerns about the bi-ventricular pacing function of the device.

Hardware

The hardware used in these systems is identical to the ICS 3000 and ERA 300/3000 with the exception of the following differences:

1. Different branding (Reliaty or Boston Scientific) on the keyboard foil
2. Different color strips on the housing
3. Different color release buttons on the battery cartridge
4. Different ON/OFF button colors
5. This system can use both external and internal power supplies. The ICS 3000 uses only external power supply and the ERA systems use internal power.
6. Accessories: Models 6653, 6646, and 3150 Patient cables; Model 6652 Adapter

New Accessories
Figures 2 – 4 show the new accessories.

MODELS 6653 AND 6646
The Models 6653 and 6646 patient cables are identical to the PK-67-S cable, cleared under K022360. The patient cables connect to the Reliaty system and branches at the other into a pacing and sensing channel. The distal end can be connected to an adapter Model 6652 or PK-155. The cables are available in lengths of 760 mm (Model 6653) and 2640 mm (Model 6646) and can be used interchangeably. (See Figure 2)

Figure 2: Model 6646 Patient Cable

MODEL 3150 PATIENT CABLE
The model 3150 patient cable is identical to the PK-141 patient cable which was cleared under K083674. It is a combination of the PK-67-L cable and the PA-4 adapter. The proximal end has a Redel plug and the distal end is equipped with alligator clips. It is for dual chamber use but can be used for single chamber applications. It has a total length of 2800 mm. (See Figure 3)

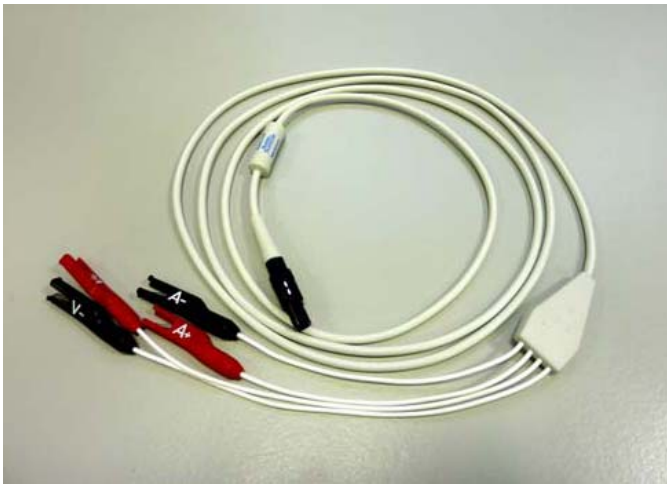

Figure 3: Model 3150 Patient Cable

MODEL 6652 ADAPTER

The model 6652 adapter is identical to the PA-4 adapter cleared under K022360. It is used to connect either the PK-67-L/Model 6646 or PK-67-S/Model 6653 patient cables to the sensing and pacing leads. The adapter consists of four alligator clips.

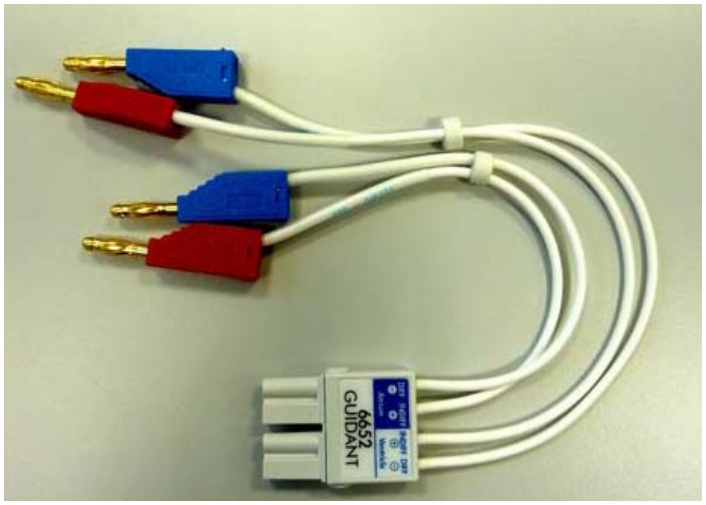

Figure 4: Model 6652 Adapter

Power Supply

The Reliaty uses a medical AC-DC external power supply module (FRIWO FW 7555M/08) as the primary source of power. The external power supply module is intended for input voltages between 100 and 240 V and frequencies between 50 and 60 Hz, and can be used worldwide. Modules of the same series but different voltages are already used with the CardioMessenger, approved through PMA Supplement P950037/S031 and the CardioMessenger II, approved through PMA Supplement P050023/S001.

The device can also use eight standard non-rechargeable AA batteries as a secondary power source. The battery type used is Duracell MN1500, type AA/LR6. The batteries are stored in two battery cartridges with four batteries per cartridge. The batteries can provide a service time of at least twelve hours under the following standard operating conditions:

- Dual-chamber pacing
- A pacing amplitude of 5.0 V
- At 500 Ohm pacing impedance
- Without Bluetooth printer operation
- Without active VGA port
- A pacing rate of 70 ppm
- A pacing width of 0.5 ms
- With long-life illumination setting
- Without USB flash memory stick
- At a battery temperature of 20 – 25 °C

The firm has provided extensive validation testing for both the internal and external power source. Testing was conducted in accordance with FDA recognized standards and all items passed. A more detailed review is provided in Section IV of this memo.

This information is adequate and I have no further questions or concerns.

IV. Validation Testing

EMC and Electrical, Mechanical, and Thermal Safety

The Reliaty/Model 3145 was tested by an independent CB testing laboratory, (b) (6), to verify compliance with IEC 60601-1: *Medical electrical equipment, Part 1: General requirements for basic safety and essential performance*. They also have identified the differences in ANSI/AAMI 60601-1 and performed the additional required testing. The results of the testing indicated that the Reliaty/Model 3145 Pacing System Analyzer is in compliance with the current standard. As a subset to this testing the same laboratory verified compliance with IEC 60601-2-31: *Medical electrical equipment: Particular requirements for the safety of external cardiac pacemakers with internal power source*. The results of the testing state that the external pacing functions of the Reliaty device are in compliance with the current standard. The CB Test Reports and results are provided in Appendix 69.

I have reviewed the standards documents, test reports, test exclusions, and anomalies and agree that the device performs in accordance with all applicable sections of IEC/ANSI/AAMI 60601-1 and IEC 60601-2-31.

Performance Testing – Bench

In addition to testing for compliance with standards, Biotronik performed the following verification and validation bench testing:

1. (b) (4)
2. (b) (4)
3. (b) (4)
4. (b) (4)
5. (b) (4)
6. (b) (4)
7. (b) (4)
8. (b) (4)
9. (b) (4)

10. (b) (4)
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20. (b) (4)
21. (b) (4)
22. (b) (4)
23. (b) (4)
24. (b) (4)
25. (b) (4)
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27. (b) (4)
28. (b) (4)
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31. (b) (4)
32. (b) (4)
33. (b) (4)
34. (b) (4)
35. (b) (4)
36. (b) (4)
37. (b) (4)
38. (b) (4) vals
39. (b) (4)
40. (b) (4)

41. (b) (4)
42. (b) (4)
43. (b) (4)
44. (b) (4)
45. (b) (4)
46. (b) (4)
47. (b) (4)
48. (b) (4)
49. (b) (4)
50. (b) (4)
51. (b) (4)
52. (b) (4)
53. (b) (4)
54. (b) (4)
55. (b) (4)
56. (b) (4)
57. (b) (4)

A summary of each test is provided in Section 8.1.3 of the main submission and the full test reports are provided in Appendicis 6 – 70 and Appendix 80. I have reviewed the submitted information and it is adequate.

V. Biocompatibility

This section is not applicable because neither the device nor any of the accessories make patient contact.

VI. Software

Version: M2_7_0		
Level of Concern: Major		
	Yes	**No**
Software description: A detailed description can be found in Sections 4.4 and 4.5	x	
Device Hazard Analysis: Separate hazard analysis reports for the PSA and patient cables are provided in Appendicis 2 and 3 respectively. Appendix 4 contains the overall risk management plan.	x	
Software Requirements Specifications: Provided in Appendix 1	x	
Architecture Design Chart: The firm has not provided an overall design chart but has given a detailed description of the software change process from the original ICS 3000 software. This is adequate.		x
Design Specifications: Section 4.4 of the main file and Appendix 1	x	
Traceability Analysis/Matrix: Appendix 4	x	
Development: Section 7 of the main file	x	

Verification & Validation Testing: A summary of testing is provided in Table 14 of the main submission starting on page 62 of 70. The individual test reports are provided in Appendicis 71 – 82.	x	
Revision level history: Appendix 1	x	
Unresolved anomalies: Appendix 5. Biotronik lists 12 unresolved anomalies all of which have low clinical significance and do not affect any therapeutic functions.	x	

(b) (6) clinical consult reviewed the user interface and usability of the software regarding specific clinical issues. In particular she reviewed sections 4.4 and 4.5 of the submission. She had one question (deficiency 4 of her review memo) in Section 4.4 which was addressed interactively and the firm's responses are provided as Attachment 2 to this memo. (b) (6) and I discussed the responses during a phone call on August 4, 2010. We agree that they are adequate and have no further concerns about the software design or user interface.

The software update and development process is described in Section 7 of the main submission. Their process is designed in accordance with FDA-recognized standard IEC 62304, *Medical Device Software – Software life cycles processes*. They conducted and passed validation testing to confirm that they are in compliance with this standard and the test report is provided in Appendix 81. They address:

1. Plan for Software development
2. Specification of Software requirements
3. Verification of Software requirements
4. SW High level design
5. SW Detailed design
6. SW Unit tests
7. SW Risk assessment
8. SW Risk Verification

The documentation flows from design specifications → software requirements specifications (SRS) → SRS Verification → design validation.

The new design specifications are described in 4.4 and 4.5 of the main submission. The corresponding additional software requirements (SRS) are specified in Appendix 1. The itemized list on pages 4 – 22 of Appendix 1 describes SRS ID numbers SRS-(b) (4)-(b) (4) to SRS-(b) (4); hereafter referred to as SRS (b) (4) to (b) (4). This is essentially a list of SRS numbers (b) (4) through (b) (4).

While the firm did not provide a traceability matrix listing each individual SRS, each test in Appendicis 71 – 82 lists the SRS items it is designed to verify. I have reviewed the test reports and all SRS items ((b) (4) to (b) (4)) have been addressed in the verification and validation testing. I have also reviewed these Appendicis for overall design and system level validation and they are adequate.

Finally, Biotronik has provided hazard analysis documentation and documentation of unresolved anomalies. I have reviewed the information and it is adequate.

VII. Sterilization/Shelf life/Packaging

Only the cable and adapter accessories are provided sterile – the device itself is not.

The sterilization for the Reliaty/Model 3145 accessories is identical to sterilization used for the approved ICS 3000 Implant Module predecessor accessories. The general sterilization validation has been performed on a variety of products including pulse generators, leads, and adapters.

The Reliaty/Model 3145 accessories are sterilized with Ethylene Oxide (EtO) gas to a sterility assurance level (SAL) of 1x10-6. Sterilization is performed in a (b) (4) automatic sterilizer. The environmental controls, sterilization process, and sterility assurance procedures are identical to those used for other BIOTRONIK cleared pacing system analyzer and implant module accessories.

The accessories, PK-67-L/S, Model 6653, Model 6646, PK-141, Model 6652 and the PA-4 adapter used with the pacing system analyzers are sealed within a sterile blister package consisting of PETG copolyester 6763. The blister packs are sealed with a Tyvek® covering. The Tyvek® pores are permeable to sterilization gas and water vapor, but are impermeable to bacteria. These sterile packaging materials fulfill the requirements of a non-toxic reaction with the enclosed products, as well as compatibility with the ethylene oxide sterilization process.

Additionally, some of the cables and adapters (PA-2 and PA-1-B) are provided within double bags. These bags have a clear PE/PET (polyethylene/polyethylene teraphthalate) plastic front, are sealed with a medical paper backing, and then sterilized by exposure to Ethylene Oxide gas (EtO). The PK-155 cable is packaged in a single Tyvek® pouch that is also sterilized by exposure to Ethylene Oxide gas (EtO).

The shelf-life for the cables and adapters is 2 years which is the same as accessories to the ICS 3000.

VIII. Labeling

(b) (6) provided a consulting review of labeling and her review memo is included as Attachment 1. She had a number of deficiencies that were addressed interactively. Biotronik responded to each deficiency in a July 30, 2010 email (Attachment 2).

(b) (6) and I discussed the responses during a phone call on August 4, 2010. We agree that they are adequate and have no further concerns about the labeling.

IX. Deficiencies: None

Attachments:

1. Clinical review memo from (b) (6)
2. 7-30-10 Email response from Biotronik

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Memorandum

Clinical Consult

To: (b) (6)
From: (b) (6) M.D.
Cc: Mitchell Shein
Date: July 2, 2010
File: P950037 S079 and P950037 S079 A001
Sponsor: Biotronik Inc.
Device(s): Reliaty/ Model 3145 family of PSA

Materials Reviewed
P950037 S079
P950037 S079 A001

P950037 S079

Background of submission
The sponsor submitted P950037 S079 to request permission to market the Reliaty/Model 3145 Pacing System Analyzers (PSA). However, during discussion with FDA, it was recommended that the labeling clearly state that these PSA's only be used during the device implant procedure. The sponsor has agreed to change the labeling and this was submitted as P950037 S079 A001.

The Reliaty and Model 3145 PSAs are essentially identical but the Reality is planned to be distributed by Biotronik and #3145 is planned to be distributed by BSC.

Proposed Indications for Use
"This device is indicated for use in pacing lead system analysis during the implantation of pacemakers and defibrillators."

Reviewer Comments: This IFU is different from the IFU for prior Biotronik PSA's which were specific to Biotronik devices or specific to pacemakers.
This IFU seems acceptable and clearly indicates that it is only for use during the implant procedure.

Contraindications
Section 2.2 includes"Use as an external pacemaker while the patient is left unattended."

Reviewer Comments: This statement clearly indicates that the patient cannot use this without medical personnel attention.

Device Description (section 3.0 and 4.0)

- Triple chamber PSA
- Stand alone device
- Similar to the ICS 3000 Implant Module and the Era 300/3000 PSAs
- Can generate report of lead values
- Can deliver emergency VVI pacing
- Can be powered by external power supply or by batteries (new feature)
- Cables and adapters are identical to those used with ICS 3000 (table 10). Those for BSC will have different marking/labeling (Models 3150, 6653, 6646, PK-155, 6652)
- There are no new functions with this PSA compared to the other models
- There is a new input filter characteristic from sin-pulse to Cenelec-pulse. This may cause slightly different values between different PSAs.
- Can burst pace from the A or V which is not a new feature
- The Refractory Period A and V Stimulation Active is fixed at 425 and 250 ms respectively rather than programmable as in the other PSAs.
- The upper tracking rate and Blanking after A/V pace are fixed at 141 and 125 ms respectively
- The Reliaty version does not require confirmation window prior to STAT pacing.
- The last 15 patient tests will be automatically stored.
- Burst pacing does have a confirmation screen and the user must select "ok" to proceed. It will burst pace in only 1 channel at a time and for a maximum of 30 seconds.

Reviewer's Comments:

1. On page 9/70 in section 3.0, it states that the "Reliaty/Model 3145 is used to gather intracardiac data such as pacing and defibrillation thresholds…" It should be clarified that the Reliaty/Model 3145 does not gather data on defibrillation thresholds but rather sensing values.

Please see question #1 at bottom of review.

2. On page 11/70 in section 4.0, it states that there are 2 connector ports (one for the LA and RV and one for the LV). I believe this is meant to say RA, not LA.

Please see question #2 at bottom of review.

3. On page 11/70 in section 4.0, the sponsor states that "two connector ports…allow connection of cables linking the Reliaty/Model 3145 to the …implantable pulse generator for parameter measurements. It is not clear to this reviewer how this device is connected to a pulse generator or the purpose of this. Typically, the leads once connected to the pulse generator are assessed through a programmer.

Please see question #3 at bottom of review.

4. The changes listed in Tables 2,3,and 4 in section 4.0 comparing this PSA device to the ICS 3000 and the ERA 3000 seem fairly minor and do not pose any additional concern for safety. These changes seem acceptable.

5. Section 4.3 (Hardware Components), section 4.4 (Software Design), section 5 (Materials, Biocompatibility), section 6 (Risk Analysis), section 7 (Life Cycle Process) and section 8 (Verification and Validation) were not clinical and not reviewed by me.

6. Table 6 shows that the STAT pace feature does not require a confirmation window prior to initiation (Model 3145 does).

Please see question #4 at bottom of review.

7. The burst pacing feature seems reasonable. *See question #4.*

Proposed Labeling (Appendices 83-88)

Reliaty Technical Manual:

- IFU includes the updates wording: "This device is indicated for use in pacing lead system analysis during the implantation of PMs and defibrillators."
- The Intended Use is concordant: "Intended to be used during the implantation of PMs and defibrillators to evaluate the placement and integrity of pacing leads and to determine the appropriate pacing parameters for the implanted device."

Reviewer Comments: This Manual appears acceptable. I have no concerns.

Model 3145 Technical Manual:

The IFU and Intended Use are identical to the Reliaty Technical Manual above. The contraindications are the same.

Reviewer Comments: This Manual appears essentially identical to the Reliaty Manual except for the marking on the PSA stating Boston Scientific and the STAT pacing having a confirmation window.

Model 3150 Technical Manual (patient cables):
Reviewer Comments: This manual is appears acceptable.

Reliaty/ Model 3145 Additional Labeling (Quick Reference Guide):
It states that the PSA is "for intraoperative diagnostics during implantation of pacemakers and ICS systems. It also refers the reader to the User Manual.

The Reliaty and Model 3145 appear identical except for the Boston Scientific marking.

P950037 S079 A001

Changes to the Technical Manual

<u>The proposed change in labeling for the Intended Use (p.7):</u>

This device is intended ~~to be used~~ for use during the ~~implantation~~ implant procedure of pacemakers and defibrillators ~~to evaluate~~ for the evaluation of the placement and integrity of pacing leads ~~and to~~ in order to determine the appropriate pacing parameters for the implanted device.

Only trained medical personnel may use ~~the~~ this device. While the device is in use, the medical staff must continuously monitor the patient with ~~the aid of~~ a surface ECG monitor, and emergency resuscitation equipment must be readily available.

~~In support of this intended use, the~~ The device provides the following measurement/diagnostic capabilities:

- For ~~the~~ sensing ~~of~~ intrinsic events ~~of the heart~~:
  - P/R wave amplitudes and slew rate
  - Rates (PP, RR interval)
  - Intrinsic AV delay (PR interval)
  - Conduction times
  - Wenckebach point
  - VV delay
- For ~~the~~ pacing ~~of the heart~~:
  - Pacing thresholds in up to 3 chambers
  - Lead impedances
  - Burst pacing

Note: During the ~~implantation~~ implant procedure, the ~~device~~ Reliaty PSA can temporarily take over the pacing functions of a ~~cardiac~~ pacemaker ~~for the pacing~~ in up to 3 chambers of the heart.

<u>Proposed Change in Labeling to the Contraindications:</u>
"Use as an external pacemaker." has been revised to:
"Use as an external pacemaker outside of the implant procedure."

<u>Reviewer's Comments:</u> I believe these changes to the labeling regarding Intended Use and Contraindications are sufficient to clearly convey that this device is for use in the EP lab or O.R. during the implant procedure only. I believe these changes address FDA's concerns and are acceptable.

Questions/Deficiencies

1. In section 3.0 of this PMA/S, you state that the "Reliaty/Model 3145 is used to gather intracardiac data such as pacing and defibrillation thresholds…" Please clarify whether this device gathers data on defibrillation thresholds or not. If this PSA does not gather data on defibrillation thresholds, please reword this section to better convey device function.

2. On page 11/70 in section 4.0, it states that there are 2 connector ports (one for the LA and RV and one for the LV). Please clarify if you intended to say "RA" rather than "LA" and revise text as necessary.

3. On page 11/70 in section 4.0, you state that "two connector ports…allow connection of cables linking the Reliaty/Model 3145 to the …implantable pulse generator for parameter measurements. Please explain how this PSA device via cables connects to pulse generators. Please also explain what purpose this serves since typically leads connected to the pulse generator header are typically assessed with a programmer, not a PSA.

4. Table 6 shows that the Reliaty PSA model will not require a confirmation window prior to initiating STAT pacing. Is this identical to how the STAT pace feature functions in the ERA 3000 and ICS 3000 or do those PSA devices require a confirmation window? Please also confirm that the burst pacing feature is identical to the ERA 3000 and ICS 3000 PSA devices.

Summary

Overall, this PSA device is not very different form currently available Biotronik PSA's.
My questions listed above are relatively minor in scope.
Although I would ask the sponsor the questions I listed, I believe this file is APPROVABLE.

(b) (6) [redacted]

From: Asusena Cobarrubias [asusena.cobarrubias@biotronik.com]
Sent: Friday, July 30, 2010 2:43 PM
To: (b) (6) [redacted]
Cc: Marianne Jacklyn; Jon Brumbaugh; (b) (6) [redacted]
Subject: Re: Fw: P950037/S079 Reliaty PSA
Importance: High

Hi (b) (6) [redacted],

Per your email request, please see the following responses to your questions (indicated in bold print) regarding the Reliaty PSA (P950037/S079):

1. In section 3.0 of this PMA/S, you state that the "Reliaty/Model 3145 is used to gather intracardiac data such as pacing and defibrillation thresholds…" Please clarify whether this device gathers data on defibrillation thresholds or not. If this PSA does not gather data on defibrillation thresholds, please reword this section to better convey device function.
No, the Reliaty PSA does not test defibrillation thresholds. This was an overlooked error in the submission text. We apologize for this inconvenience. Please find the revised section text below in blue with the changes in bold and underlined:

Currently, BIOTRONIK markets the ICS 3000 Implant Module that was approved through PMA Supplement P950037/S43, on April 24, 2006. The ICS 3000 Implant Module is a triple chamber pacing system analyzer. The functionality of the Reliaty/Model 3145 is identical to this device; however, the Reliaty/Model 3145 is a stand alone version of it. Like the Implant Module, the Reliaty/Model 3145 is used to gather intracardiac data such as **pacing thresholds**, and lead impedance prior to the connection of the pacemaker or ICD. Both devices can also measure the timing parameters (e.g., AV delay, VV delay) of the patient and lead system.

2. On page 11/70 in section 4.0, it states that there are 2 connector ports (one for the LA and RV and one for the LV). Please clarify if you intended to say "RA" rather than "LA" and revise text as necessary.
Yes, the "LA" in this section should have been "RA"; we apologize for this inconvenience. This was a typo in the submission text. Please find the revised section text below section text below in blue with the changes in bold and underlined: (this text has also been revised per the response to Question #3 below):

Two connector ports (one for the **RA** and RV and one for the LV) on the back of the pacing system analyzer allow connection of cables linking the Reliaty/Model 3145 to the lead system for pacing and lead system tests. The cables and adapters for use with the Reliaty/Model 3145 are identical to those approved for use with the ICS 3000 Implant Module, ERA 3000 and the ERA 300. The Boston Scientific Model 3145 cables and adapters are mechanically identical to the corresponding BIOTRONIK Reliaty cables and adapters; they are also identically packed and sterilized. Section 4.7 describes the accessories to the Reliaty/Model 3145 systems.

3. On page 11/70 in section 4.0, you state that "two connector ports…allow connection of cables linking the Reliaty/Model 3145 to the …implantable pulse generator for parameter measurements. Please explain how this PSA device via cables connects to pulse generators. Please also explain what purpose this serves since typically leads connected to the pulse generator header are typically assessed with a programmer, not a PSA.
No, the Reliaty PSA cannot be connected to the pulse generator; it can only be connected to the patient's leads. Testing the pulse generator with a PSA is no longer a common practice by physicians during the implantation

procedure. Therefore, only the older PSAs like the ERA 300 and 3000, can be connected directly to a pulse generator.

4. Table 6 shows that the Reliaty PSA model will not require a confirmation window prior to initiating STAT pacing. Is this identical to how the STAT pace feature functions in the ERA 3000 and ICS 3000 or do those PSA devices require a confirmation window? Please also confirm that the burst pacing feature is identical to the ERA 3000 and ICS 3000 PSA devices.

Yes, the Reliaty PSA does not have a confirmation window before starting the STAT (VVI) pacing. This STAT feature is identical to that of the ERA 300 and 3000, as well as the ICS 3000 Implant Module (IM).
The intended use of the Burst Pacing feature is identical in both the Reliaty and ICS 3000 IM PSA devices. However, the burst feature in the Reliaty PSA is used only to terminate tachycardia episodes; whereas, the IM has an additional burst function used to induce fibrillation when determining defibrillation thresholds. The Burst Pacing feature's settings are slightly different between these devices. The Reliaty can pace at a rate of (b) (4) ppm (adjustable) or (b) (4) ppm (preset) with a fixed (b) (4) V amplitude and (b) (4) ms pulse width for a maximum of (b) (4) seconds; the ICS 3000 IM and the ERA 300/3000 have (b) (4) ppm and programmable amplitude and pulse widths, but no automatic termination after (b) (4) seconds.

Best Regards,
Asusena

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Jon Brumbaugh/BIO-US/BIOTRONIK

07/23/2010 02:09 PM

To "Ms. Asusena Cobarrubias" <asusena.cobarrubias@biotron k.com>
cc Marianne Jacklyn/BIO-US/BIOTRONIK
Subject Fw: P950037/S079 Reliaty PSA

Fyi

From: "(b) (6)" [(b) (6)@fda.hhs.gov]
Sent: 07/23/2010 05:05 PM AST
To: Jon Brumbaugh
Cc: "(b) (6)" <(b) (6)@fda hhs.gov>
Subject: P950037/S079 Reliaty PSA

Hi Jon,

Here are the questions I referred to in my voice mail from this afternoon.

1. In section 3.0 of this PMA/S, you state that the "Reliaty/Model 3145 is used to gather intracardiac data such as pacing and defibrillation thresholds…" Please clarify whether this device gathers data on defibrillation thresholds or not. If this PSA does not gather data on defibrillation thresholds, please reword this section to better convey device function.

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3. On page 11/70 in section 4.0, you state that "two connector ports…allow connection of cables linking the Reliaty/Model 3145 to the …implantable pulse generator for parameter measurements. Please explain how this PSA device via cables connects to pulse generators. Please also explain what purpose this serves since typically leads connected to the pulse generator header are typically assessed with a programmer, not a PSA.

4. Table 6 shows that the Reliaty PSA model will not require a confirmation window prior to initiating STAT pacing. Is this identical to how the STAT pace feature functions in the ERA 3000 and ICS 3000 or do those PSA devices require a confirmation window? Please also confirm that the burst pacing feature is identical to the ERA 3000 and ICS 3000 PSA devices.

I'll touch base with you when I get back in town on the 2nd and maybe we can take care of them interactively.

Have a good weekend.

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