SUMMARY of P950037/S084
Reocor S/D Families of External Pacemakers
Biotronik, Inc.

I. Purpose and Submission Summary

This 180-day PMA-S is requesting approval for the Reocor S/D Family of External Pacemaker Pulse-Generators. The new device represents further development of their EDP 30/BP and EDP 20/B temporary external pacemakers.

II. Device Description

Reocor is a battery powered external pacemaker that is used in combination with a lead system for temporary atrial, ventricular and AV – sequential stimulation in a clinical environment. The Reocor is a product family of external pacemakers. These pacemakers are used for temporary pacing.

Temporary pacing with Reocor is indicated for the following applications for patients of any age:

- Temporary treatment of arrhythmias and heart block
- Symptomatic sinus bradycardia
- Pre-, intra-, and postoperative temporary stimulation of patients undergoing cardiac surgery
- Termination of supra-ventricular tachyarrhythmias.
- Prophylactic pacing for prevention of arrhythmias
- Emergency pacing
- Checking the pacing thresholds

The majority of functional properties of the predecessors EDP 20B (external single chamber pacemaker) and EDP 30B (external dual chamber pacemaker) have remained unchanged in Reocor.

The main difference to the predecessor is that the Reocor provides the possibility to connect heart wires directly to the device. Temporary catheters, heart wires and leads with 2-mm plugs can be connected directly to the Reocor device. The connection can also be made via a separate patient cable and adapter, identical to the predecessor devices.

The Reocor is distributed in two different versions. One single chamber pacemaker model named “Reocor S” and one dual chamber pacemaker model distributed under the trade name “Reocor D.”

The pacing mode, rate, sensitivity and pulse amplitude, AV delay and burst rate are adjustable. LEDs display the sense (Sense), pace (Pace) and battery status (Low battery).

An audible signal sounds when a very high frequency or very low sensitivity value is set and when the lead impedance is not optimal. The device is applied to an infusion stand, the patient's bed or the patient via an arm band and has no direct contact with the body of a patient. The external pacemaker interacts with the patient via accessory cables or catheters described below.

Figure 1 below provides a front view of the controls of the Reocor.

Figure 1: Reocor D External Pacemaker

Accessories

- BIOTRONIK's PK-141, PK-175, PK-82, PK-83, PK-83-B, PK-67 or similar cables with patient adapters or PK-155 (for further information regarding these cables please see Section 4.4), applied to heart wires.
- a temporary catheter like TC-114
- This system offers a secure connection of transvenous catheters and myocardial leads, which are applied either as unipolar or bipolar. Additionally, the Reocor family of external pacemakers is intended for short-term use by physicians, cardiac technicians and nurses in a hospital setting.

Table 1: Accessory Cables and Adaptors

Accessory	Description	PMA or 510(k)
BIOTRONIK Accessories for Reocor		
PK-155	Patient cables (2) with alligator forceps for single use, sterile	K022360, dated January 27, 2000
PK-141	Patient cable with alligator forceps, sterile, Resterilizable	K083674, dated April 1, 2009

PK-82	Patient cable with 2 isolated alligator clips, resterilizable	P950037/S21. dated 9/10/01
PK-83	2 Screw connectors, resterilizable	K022360, Dated 1/27/03
PK-83-B	2 Screw connectors on patient side and one Redel connector on the device side	K022360, Dated 1/27/0
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-1-C	Adapter for Touch-proof 2mm pins and MHW-Adapt	P950037/S43, dated April 24, 2006
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
Remington Medical Accessories		
Model 301-CG	Patient cables (2) with alligator forceps for single use, sterile	K971968
Model S-101-97	Single use cable, 2 wire with alligator clips	K971968
Model FL-601-97	Single use cable, 2 wire with screw terminals	K971968
New Accessories		
Redel-Adapter Reocor S	Interface for Biotronik cables with Redel-Connector	Subject of this submission
Redel-Adapter Reocor D	Interface for Biotronik cables with Redel-Connector	Subject of this submission

III. Description of Changes

The major difference between the EDP device and the Reocor is that with Reocor the pacing wires can connect directly to the device. The connection can still be made with a separate cable and adapter as in the predecessor. Other differences are presented in Table 2 below and include: (1) Reocor has a trigger mode (VVT, SST) which was not previously available; (2) Reocor S sensitivity goes up to 20 mV; and (3) the AV delay is programmable up to 400 ms.

The mode, rate, sensitivity and pulse amplitude are all programmable.
There is an audible signal when a high rate (>180) or when lead impedance is out of range (<100 or >3000). There is also a 2 second alert when an output <1V is set.

Burst pacing requires pressing the SELECT button and then continued holding down of the START button.

There are several cables, adapters and accessories that can be used with the Reocor device. There are 2 items that are part of this PMA/S; (1) Redel adapter Reocor S and (2)

Redel Adapter Reocor D which both allow an interface between Biotronik cables and the Redel connector. Table 2 shows a side-by-side comparison.

Table 2: Device Comparison

Parameter	Unit	EDP 30	Reocor D	Reocor S	EDP 20
Adjustable Parameters					
Stimulation mode	No	DDD, VDD, DVI,D00; VVI,VOO	DDD,DOO, VDD, VVI; VOO, VVT	SOO, SSI, SST	VVI, VOO
Basic rate	ppm	30-250			40-180
Pulse amplitude	V	0.1 – 12	0.1 – 17		0.1 – 12
Sensitivity Atrium	mV	0.2 - 10		1 – 20	N/A
Sensitivity Ventricle	mV	1 – 20			
AV delay	ms	15 – 250	15 – 400	N/A	N/A
Burst frequency	ppm	50 – 1000	60 – 1000		50 – 1000
Pacing Configuration	None	unipolar or bipolar			
Non-Adjustable Parameter					
Pulse width	ms	0.9	1.0	1.0	0.9
Auto short after pace	ms	20	<20		N/A
Noise Interval	ms	125			
In Channel Blanking	ms	80	110		N/A
Refractory period					
Total refractory period (TARP)	ms	AVD + 225	AVD + 175	N/A	N/A
TARP minimal					
30 – 120 ppm	ms	400		N/A	
121 – 250 ppm	ms	240		N/A	
Ventricle					
30 – 150 ppm	ms	225			N/A
151 – 200 ppm	ms	200			
201 – 250 ppm	ms	175			
Upper tracking rate	ppm	315	260		N/A
High Rate Protection	ppm	176 _ 340 ms	1…180 _286 ms 181…250 _ 214 ms		40..99 _ 500 ms 100..180 _300 ms
Pulse form	None	asymmetrical, biphasic			
Storage and Operating Conditions					
Storage Temperature	°C	-10 – +50	0 – +50		-10 – +50
Operating Temperature	°C	-10 – +40	+10 – +40		-10 – +40

Additional Data					
Engery Supply	V	9			
Operation Time on Fully Charged Battery	Hours	~400	500	600	~900
Low Battery Behavior	None	red, flashing LED			
Degree of Protection	None	CF (cardiac floating, defibrillator protected)			
Dimensions (W x L x H)	Mm	147 x 70 x 27	75 x 160 x 35 (without Redel adapter)		147 x 70 x 27
Weight (with battery)	gm	250	220	205	250

A. Clinical

The clinical consultant reviewed the new device features for their clinical impact resulting in the following questions:

1. What is "High Rate Protection"?
2. What is the advantage to having trigger modes (VVT) in a temporary pacemaker? According to table 1, the trigger modes (VVT, SST) are new modes and not available in the EDP 30 but table 8 states there are no new stimulation modes. Are these modes a new feature or were they available in the EDP 30?

Amendment 1 addressed each of the items. The clinical consultant also reviewed the updated User's Guide provided in A002. This consultant believes that the responses are adequate and has no questions or concerns about the labeling or User's Guide.

B. Hardware

Sections 4.1 and 4.3 of the original submission contain a thorough description of device hardware, functions, and operation. Pages 13 of 50 and 14 of 50 show the front panels of each model with a description of each control on the operating panels.

Sections 4.3.1 to 4.3.15 discuss:

- Device protective cover
- Power mode selection dials
- Rate dials
- Sensitivity dials
- Burst pacing dials
- Pulse amplitude dials
- LED battery indicators
- LED sense and pace indicators
- Interference interval
- Self-test
- Lead impedance audible warning
- High rate pacing warning

- Polarity
- AV delay dial, refractory periods, and cross channel blocking

Only the protective cover is new to this device. Both the clinical consultant and lead reviewer have reviewed these functions. There are no further questions or concerns.

C. New Accessories
Figure 2 shows the new accessories.

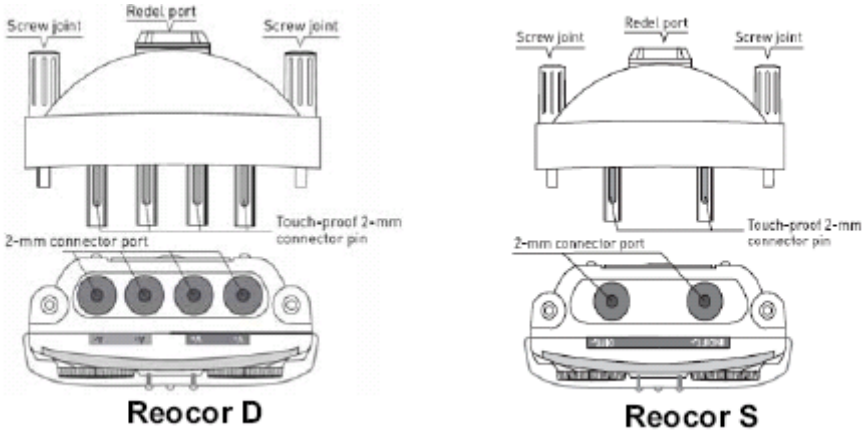

Figure 2: Redel Adapters

The Redel adapter gives the ability to connect patient cables with Redel plugs to the Reocor. The Redel adapter is plugged into the correct side of the respective Reocor device and then screwed into place.

D. Power Supply
This device uses a 9 Volt battery, international code IEC 6LR61. The labeling states that only alkaline manganese batteries should be used and recommends Type MN 1604 batteries manufactured by Duracell or Procell. The operation time of a fully charged battery is approximately 300 hours for the Reocor D and 600 hours for the Reocor S. When the red Low Battery LED starts flashing, it indicates that approximately 36 hours of service time remains. Biotronik has included this information in the labeling and adequately described the battery requirements.

E. Device Modifications Submitted in A001

1. Reinforced Battery Contacts – This Amendment includes a modification to the battery connectors in order to reinforce them. The product specifications were revised to state that no mechanical damage should occur if the device falls off a height of 1.50 m. A removable rubber protection or similar accessories can be provided to protect the device. The new product requirement was implemented due to a field complaint that observed device damage after a fall of significant height. In order to prevent these types of failures, the battery connector reinforcement was added.

The validation testing for this change is reviewed in Section IV of this review memo. The change does not raise new safety concerns and adequate validation testing data has been submitted. There are no further questions or concerns.

2. Software Parameter Change for Lead Impedance Monitor – this is a modification to the software parameter settings for the audible lead impedance warning signal. Each pacing pulse is monitored by the device to detect changes in the lead impedance. If the measured impedance is not within the specified range a sequence of alarms begins no earlier than 5 seconds after activation.

   The impedance range is 200 – 2000 Ω, at >1 V amplitude. An audible warning will sound when the monitored impedance is less than 100 Ω or greater than 3000 Ω with a transition range of 100 – 200 Ω or 2000 – 3000 Ω, respectively. If the pulse amplitude is set to less than 1 V, an audible warning signal will sound for two seconds. It will also change the threshold of the low impedance warning to half of the transition range (100 Ω and 200 Ω). With this change, the software version was updated to version C_3_16_1. This update is only for the lead impedance monitoring change, no other changes were made to this software version. There are no further questions or concerns.

3. Software Programming Change to Potentiometer Parameters – Each control knob on the front of the device (See Figure 1 above) is directly connected to a potentiometer. The value displayed by the potentiometer corresponds to the angle of the control knob and therefore indicates the device setting (confirmed in 5-13-11 email from Biotronik during review of A001). There are no further questions or concerns.

4. Technical Manual Corrections – Biotronik has added 5 statements to the technical manual of each of the device models. There are no further questions or concerns.

F. Responses to FDA Deficiencies

Biotronik has responded to both deficiencies identified in FDA's 12-12-11 letter. The clinical consultant and lead reviewer reviewed the following responses:

1. **EN 45502-2-1**: The sponsor agrees that the EN 45502-2-1 Standard is indicated for active implantable medical devices (AIMD) and is not applicable to the Reocor S/D external pacemakers. As discussed during the January 19th Conference Call, the sponsor conducted EN 45502-2-1 testing for informational purposes. Biotronik also clarified that the sections of the standard deemed applicable to external pacemakers were used in developing the test set-up for verifying functionality. Additionally, Biotronik confirmed that this European Standard allows the use of a labeling mitigation for any observed interference during the testing. They have provided a complete list (see Section IV of this memo) of the testing performed according to IEC 60601-2-31 and 60601-1-2 which apply more directly to this device. The response is adequate.

2. **Functionality during EMI**: The sponsor has clarified that this setting (≤1mV) sensitivity is only available in the atrial channel of the dual-chamber Reocor D external pacemaker. The single chamber Reocor S external pacemaker cannot be programmed to less than 1 mV. The test results in Appendix 1 and Appendix 2 of A002, demonstrate that the Reocor S/D does function properly when exposed to normal clinical environments according to the intended use. The sensitivity curve of the atrial channel in Appendix 1 (Table 2) functions per settings and as defined in EN 45502-2-1 (ISO 14708-2) at all required frequencies, except the range between 20 - 400 Hz. In the event of interference within this frequency range, the dual-chamber Reocor D device automatically switches to an asynchronous pacing mode as designed. The risk assessment shows that a permanent interference in the specific frequency range and voltage level, between the normal operation mode and the interference mode is rather low. As an additional mitigation, the labeling indicates that the patient is to be monitored via an ECG with an alarm signal. Given the intended use environment, this mitigation step is (and has been) generally acceptable for temporary external pacemakers. The response is adequate.

IV. Validation Testing

EMC and EMI

A consulting review for Electromagnetic Compatibility and Electromagnetic Interference was provided for this file.

The Reocor external pacemakers passed the EMC and CB testing performed by the external testing laboratories, (b) (4) The sponsor provided the following testing in A001 in accordance with the IEC 60601 standards cited:

- Appendix 1 – (b) (4) EMC Test report performed according to EN 60601-1-2:2007 & EN 60601-2-31:2008
- Appendix 3 – (b) (4) CB Test report performed according to IEC 60601-1:2005
- Appendix 4 – (b) (4) CB Test report performed according to IEC 60601-2-31:2008 (in conjunction with IEC 60601-1:2005)

The EMC testing also follows the FDA draft guidance "Class II Special Controls Guidance Document: External Pacemaker Pulse Generator," issued on October 17, 2011:

1. Emissions – Test reports submitted in A001 Appendix 1 and 2
2. Immunity:
    a. Electrostatic discharge (ESD) per ISO 60601-1-2 Sect. 6.2.2
    b. Radiated RF electromagnetic fields per ISO 60601-1-2 Sect. 6.2.3
    c. Electrical fast transients and bursts per ISO 60601-1-2 Sect. 6.2.4, not applicable since there is no external power supply and no signal lines more than 3 m

d. Surges per ISO 60601-1-2 Sect. 6.2.5, not applicable to Reocor S/D since there is no external power supply
e. Conducted RF electromagnetic energy per ISO 60601-1-2 Sect. 6.2.6
f. Voltage dips, short interruptions, and voltage variations on power supply input lines per ISO 60601-1-2 Sect. 6.2.7, N/A because no external power supply
g. Low-frequency magnetic fields per ISO 60601-1-2 Sect. 6.2.8
h. Quasi-static electric fields. These fields are not addressed in the ISO 60601-1-2. These types of low frequency electrical fields do not cause interferences.

The information above has been reviewed and found to be adequate.

Battery Review

The new feature is an OTC 9-V (non-rechargeable) battery is used as the sole power source for the device. The 9-volt battery has the international code IEC 6LR61.

From page 377, the sponsor has provided test results to show that a new unit of the 9-V battery provided pacing for 556 hour and 55 minutes for the Reocor D, and another new unit of the battery provided 615 hours and 20 minutes for the Reocor S, when the battery was a type MN 1604 Duracell Procell. The pacing specifications were: 500 ohm load, 70 ppm, 5 V, VVI or DDD. The labeling was amended in A001 to specify that only the type MN 1604 battery should be used.

The ERI flag is set at 6.8 V +/- 5%. A time from ERI to EOS of at least 36 hours was included in the above service life data for each external pacer. The testing was performed using 100% pacing. During operation (after the internal capacitor is fully charged), the battery can be removed from the device's battery housing for up to 30 seconds, without any interruption in the device's pacing therapy. This has been substantiated with data.

The information provided is adequate.

Performance Testing – Bench

Beginning on page 26 of the original submission Biotronik provides a summary of validation activities that includes mechanical, functional, electrical, software, manufacturing, shipping, and simulated age testing.

IEC 60601-2-31 references the performance requirements in Table 3 for external pacemaker pulse generators. The validation testing was provided in the referenced Appendix for each item.

Table 3: Distributed Essential Performance Requirements

Requirement	Appendix
Battery depletion indicator	7
ME Equipment parameter stability	14 – 28

Pulse amplitude stability	15
Disarming runaway rate protection	n/a
Deliberate action required to change settings	6 and 14
Parameter stability at onset of Battery depletion indicator	53 and 55
Runaway protection	24 and 69
Interference reversion in the presence of sensed interference	50, 51, and 52
Limit for ventricular pacing in response to atrial pacing	69

In addition they provided testing for patient auxiliary current and patient leakage current in Appendix 60 of the original submission.

The Validation testing has been reviewed and is adequate.

V. Biocompatibility

Not Applicable

VI. Software

SOFTWARE COMPONENTS

The functions and features of the Reocor D and Reocor S are controlled by the Reocor software application. The software application for the Reocor program is managed with the revision management tool, MKS Source Integrity Enterprise Edition version 8.6 or higher. Revisions of the entire software are managed through checkpoints labeled Cx-xx in the MKS system. The current software version used in the Reocor devices is C_3_16_0. Programming was done exclusively in C programming language and the hardware environment is an ARM processor. The Software Requirements Specification (PFH-115-106) with all the software requirements that were considered in the development of the Reocor devices is provided in Appendix 1 of the original submission.

The software is divided into three main modules: the bootloader module, the service application module and the user application module. Figure 3 is a block diagram that shows the functional parts of the Reocor software modules.

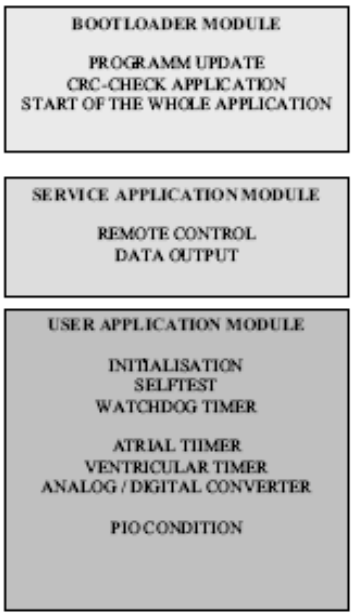

Figure 3: Architectural overview of Reocor Software Modules

RISK ANALYSIS

During the development process of the Reocor, a risk analysis was conducted. In the course of the analysis, all possible hazards associated with the design, functionality and use of the devices were determined. The risks of the known hazards have been evaluated and classified according to their likelihood and severity. If the risks were determined to be intolerable, adequate measures have been addressed to eliminate or minimize the respective likelihood and/or severity of the hazard. The effectiveness of all risk minimization measures is tested during product verification/ validation.

The risk analyses listed in Table 10 documents all risks associated with the use of the external pacemaker and an appropriate resolution. The risk management plan describes the relation between the product requirements, the associated risks, the measures of risk reduction and the proof of the effectiveness of these measures. It documents the different risk analyses and the determination of the remaining residual risk. The verification results which show the effectiveness of the risk reduction measures are listed in the risk management plan.

DEVELOPMENT LIFE CYCLE PROCESS

The Reocor application has been developed according to the complete BIOTRONIK Design Life Cycle Process rules. The design input phase provided a set of comprehensive system requirement specification documents covering the following areas: a) Therapeutic Functions, b) Electrical Requirements and c) Mechanical Requirements. The safety requirements have been derived from a dedicated risk analysis. The subsequent decomposition process resulted in appropriate software requirement specifications and design specifications in order to support the code implementation and the hardware development.

Biotronik has an established software change process as part of the life cycle model. An explanation of the software development process for the specific software updates, the verification process for the submitted changes, and the process for bug detection and correction during the verification of software updates follows:

Overview of Software Process Description: Software Change Process including Regression Testing

For the development of the software a defined and established design life cycle model is followed. This design lifecycle is comprised of all elements that are required for a rigorous software development process for newly developed code:

- Plan for Software Development -> Specification of Software Requirements -> Verification of Software Requirements -> Software High Level Design -> Software Detailed Design -> Implementation -> Verification -> Validation.
- The life cycle phases are accompanied by a parallel risk management process.

Detailed Description of the Software Process for Feature Development during Product Updates

BIOTRONIK software is developed according to requirements. Feature requirements include the functionality for the feature as well as interactions with other features. Prior to feature development, the work is planned as follows:

Requirements:

- Review software requirements for relevant requirements associated with these features.
- Review software requirements to design specification to ensure that it covers all relevant requirements.

Design:

- Update architectural design to identify the necessary interfaces.
- Update detailed design document.
- Update related software detailed design documents if interface changes to other clients are required.
- Update code.
- Modify other component code as necessary.
- Developer verification and integration testing:
    - Perform unit level testing and document results.
- Code and Verification Review:
    - Schedule and execute a peer review of the code and software verification results.

The software verification and validation testing for the Reocor software application is provided in Section 9.2.1 of the submission.

VERIFICATION AND VALIDATION TESTING

The subsystem and system verification is an essential part of the design process and ensures the functionality of all subsystems and system. The testing was carried out

according to verification test plans (VEBs) and the results are documented in the verification reports (VERs). The verification report has to be created with the following content: purpose of verification, requirements to be verified, acceptance/pass-fail-criteria, composition/quantity of the verification samples and responsibility for the verification tests.

BIOTRONIK begins validation testing of modified products by establishing a Validation Plan to define all test steps necessary to prove the design safety and efficacy. Each Validation Summary references the applicable steps of BIOTRONIK developed validation plans deemed applicable and required to sufficiently validate the new or modified product. The Reocor was evaluated according to BIOTRONIK internal Validation Plans to demonstrate conformance to the design requirements, specifications and safety standards.

The test results referenced in this submission are in the form of validation evaluation results (VERs). Each test result details the testing performed, equipment used, specification(s) followed and the actual test results. All test reports are referenced in a VAN and approval (sign-off) of a VAN signifies final release of the product. Each test result details the test procedure performed, equipment used, specification(s) followed, Pass/Fail criteria, and the actual test results. Particularly, the effectiveness of risk mitigations as required by the risk analyses has been tested during the entire composition process. Those test results were summarized in the Risk Management Plan document (RMP).

All validation testing for the Reocor External Pacemakers have been successfully completed as summarized in Table 11 of the submission.

KNOWN ANOMALIES REPORT

During the validation process, all bug reports were assessed and no minor deviations in the system as compared to the specifications were found. Therefore, it was determined that a Known Anomalies Report is not applicable.

REOCOR VALIDATION TESTING

The Reocor family of external pacemakers has been subjected to validation testing to ensure final device function and reliability. The Reocor has passed all validation tests as summarized in Table 11 of the submission, and the test reports are included within the referenced appendices. Each test report details the testing performed, equipment used, specification(s) followed and the actual test results.

DOCUMENTATION SUBMITTED

Appendix 1 EDP Successor/Software System Specifications PFH-115-106
Appendix 2 Risk Analysis: EDP N, #7117 RAN-115-023
Appendix 3 Risk Analysis Patient Cables RAN-123-006
Appendix 4 Risk Management Plan: EDP N, #7117 RMP-115-027

Appendix 62 Compliance With Standards and Directives VER-111-09-1117
Appendix 63 Programmable electrical medical systems (PEMS) VER-111-08-1439
Appendix 64 Programming Language VER-111-08-1788
Appendix 65 Software Module Structure Check VER-111-08-1789
Appendix 66 Revision Administration VER-111-08-1790
Appendix 67 Plausibility Test VER-111-08-1795
Appendix 68 Function-Monitoring VER-111-08-1796
Appendix 69 High-Rate-Protection VER-111-08-1797

James has no questions or concerns about the software of this device. I agree with his assessment and believe the information provided is adequate.

VII. Sterilization/Shelf life/Packaging

This device is not provided sterile but the following accessory cables and adapters are:

- PK-67-L Patient Cable
- PK-67-S Patient Cable
- PK-141 Patient Cable
- PK-155 (Model 301-CG) Patient Cable
- PK-175 Patient Cable
- PK-82 Patient Cable
- PK-83 Patient Cable
- PK-83-B Patient Cable
- PS-2 (IS-1) Adapter
- PA-1-B Adapter
- PA-4 Adapter
- PA-1-C

The sterilization for these accessories is identical to sterilization used for the approved EDP 30/20 predecessor accessories.

The Reocor accessories, as with all BIOTRONIK products, are sterilized with (b) (4) gas to a sterility assurance level (SAL) of (b) (4) The environmental controls, sterilization process, and sterility assurance procedures are identical to those used for other BIOTRONIK cleared accessories.

The PK-67-L/S, PK-82, PK-83, PK-83-B, PK-141 and PK-175 cables and the PA-4 adapter – as with all other BIOTRONIK pulse generators, leads and accessories – are sealed in a sterile blister package consisting of (b) (4) The blister packs are sealed with 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 (b) (4) sterilization process.

Shipping configuration validation testing with the complete device system is provided in Appendix 41. I reviewed this testing and agree that it was successful and met specifications. No sterilization product validation tests were conducted for the Reocor cables and adapters, as the test results from the predecessor devices and other accessories are also valid for the Reocor accessories.

Additionally, the 2 mm cable adapters and heart wire adapters (PA-2, PA-1-C and PA-1-B) are provided within double bags. The PK-155 is packed in a single blister pack. These bags have a clear (b) (4) plastic front, are sealed with a medical paper backing, and then sterilized by exposure to (b) (4) This is the same process used by BIOTRONIK since 1991 for US-distributed medical devices. The PK-155 cable is packaged in a single Tyvek pouch that is also sterilized by exposure to (b) (4)

I have reviewed this sterilization and packaging information and it is adequate.

Shelf Life

In the risk analysis provided in Appendix 2 the firm states that this device is assumed to have a service life of 12 years. Item 38 in Table 11 (Summary of Validation Testing) again uses the 12 year mark as the acceptance criteria for real time aging storage.

The review from Charles Ho also recommended that the firm revise their table on page 22 of A001 because the original used a formula with only 51 weeks in a year instead of 52 weeks. Over the expected 12 year life of the device the difference is negligible and I have not forwarded this concern to the firm.

The shelf life for the sterile cables and adapters is 2 years but the sponsor does not specify a shelf-life for the Reocor device. Shelf life for the battery has been provided by the battery manufacturer.

VIII. Labeling

The clinical consultant provided a review of the original labeling and the labeling in both amendments. She believes the labeling is adequate and I concur with her review.

User Manual (appendix 37)

Brief overview of how to plug in leads or cables, how to burst pace, what dials are, and how to replace the battery. It does not go into depth regarding the features.

Reocor Device Labels (appendix 70)

This label contains the Biotronik logo, the device name and the serial number.

Reocor S Technical Manual (appendix 71)

Handling Instructions discuss warnings for lead connections, precautions during use, what to do if defibrillation is needed, how to handle interference, how to interpret an

acoustic signal, the various cables and adapters. There is a section on Start Up, Battery exchange, Pacing Modes, and Maintenance.

Reocor D Technical Manual (appendix 72)
This is very similar to the Reocor S Technical Manual.
It has a product description, IFU, contraindications, handling instructions, visual and acoustic signals, operating notes, pacing modes, handling care, technical data and conformity to standards.

Proposed Labeling (appendix 73)
Labeling for Reocor and accessories was reviewed and is appropriate.

Reocor S/Reocor D Quick Reference Guide (appendix 74)
This is a quick guide to battery exchanges, optical and acoustic signals and operation and lead connections.

IX. Conclusion

The sponsor has adequately addressed all deficiencies identified by FDA and I recommend Approval of this Supplement.