6.0 510(k) Summary for the Borealis Amplifier
This 510(k) Summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990.

6.1 Submitter's Information

Name:	Bard Electrophysiology Division of C.R. Bard, Inc.
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Contact Person:	Deborah L. Herrington Regulatory Affairs Manager
Date of Preparation:	December 20, 2004

6.2 Device Name

Trade Name:	CLEARSIGN Amplifier
Common/Usual Name:	Borealis Amplifier
Classification Name:	Programmable Amplifier

6.3 Predicate Device Name(s)
C.R. Bard, Inc.: Bard Biopotential Amplifier II, K913875, November 27, 1991

6.4 Device Description
The Borealis Amplifier is a medical device intended to collect, amplify, filter and format physiological signals for transfer to a host computer system (Bard Electrophysiologic LabSystem III Laboratory) capable of recording and display of such information. The physiologic signal information is acquired from diagnostic and therapeutic electrophysiology (EP) catheters, surface electrocardiographic (ECG) electrodes, intravascular pressure transducers, intracardiac stimulators and RF ablation generators.

6.5 Intended use of the Device
The Bard Borealis Amplifier is intended to amplify and condition electrocardiographic signals of biologic origin and pressure transducer input, transmitting this information to a host computer (the Bard LabSystem [III] EP Laboratory) that can record and display the information.

The Bard LabSystem III EP Laboratory is a computer and software driven data acquisition and analysis tool designed to facilitate the gathering, display, analysis by a physician, and storage of cardiac electrophysiologic

6.6 Summary of the technological characteristics of the Borealis Amplifier as compared to the predicate device
Since 510(k) concurrence was received for the LabSystem and STAMP Amplifier, modifications have been made to the system. These modifications were made to enhance the amplifier module's manufacturability or user convenience and were deemed not to significantly alter the amplifier's overall safety and effectiveness and thus did not require new premarket notifications at the time the changes were made. Some of the changes were required for compliance with the ANSI/AAMI standard for Diagnostic Electrocardiographic Devices (EC11-1982, section 3.2.9).

1. The ECG/Pressure module as described in K913875 has been upgraded to allow channel selection capability and the addition of notch filters for noise rejection;
2. A 50/60 Hz notch filter was added to the module to filter the power line frequency and the input impedance of the module was increased from 1.6MegOhms to 10.6MegOhms;
3. The V-Lead/Pressure Plus module was configured to provide 6-lead channels only with the addition of notch filters and 2 pressure channels and the input impedance of the module was increased from 1.6MegOhms to 10.6MegOhms;
4. The layout of the Intracardiac Pressure module was converted from through-hole components to surface mount components;
5. The Stimulator Switch Plus module was upgraded to make its input sensitive to the 1.5V trigger inputs found on cardiac stimulators marketed in Europe; and
6. Various software enhancements were made for user interface ease of use.

These modifications are detailed in Section 2.2.

Various hardware and firmware upgrades have been the STAMP Amplifier made over the years to adapt to the ever-changing technology and to add user-preference features. Software changes have been implemented to address the changes in hardware/firmware. These modifications do not raise new issues of safety and effectiveness.

The technological characteristics of the Borealis Amplifier and the STAMP Amplifier are essentially the same. Although changes to hardware/firmware and software have been made, the indications for use and the risks have not changed for this device. The system does not control the delivery of therapy, it does not administer drugs, it does not perform any life-supporting or life-sustaining functions, and it does not analyze data acquired during an EP procedure.

6.7 Discussion of non-clinical tests and how the results support a determination of substantial equivalence

The applicable standards pertaining to the Borealis Amplifier are listed below. These are the standards that were for previous software versions of the STAMP Amplifier.

EN 60601-1-2: Ver 2:2001-9	Electrical Medical Device Standards
IEEE Standard 730-1995	Software Quality Assurance Plans
IEEE Standard 829-1983 (*1991)	Software Test Documentation
IEEE Standard 1012-1986 (*1992)	Software Verification & Validation Plans
IEEE Standard 830-1993	Software Requirement Specifications
IEEE Standard 1008-1987 (*1993)	Software Unit testing

Various modifications have been implemented with respect to the hardware and firmware that comprise the Borealis Amplifier. The Borealis Amplifier has been tested to the following international standards:

EN 60601-1 Electrical Safety
EN 60601-1-1 Electrical Safety System Standard
EN 60601-1-2 Electromagnetic Compatibility
EN 60601-1-4 Programmable Electrical Medical Systems
EN 60601-2-27 Electrocardiograph Equipment
EN 60601-2-34 Safety Requirements for Blood Pressure Monitoring Equipment

IEC 61000-3-2 Current Harmonics
IEC 61000-3-3 Voltage Fluctuations
IEC 61000-4-2 Electromagnetic Compatibility (EMC) Part 4 Testing & Measurement Techniques, Section 2 Electrostatic Discharge Immunity Test
IEC 61000-4-3 Electromagnetic Compatibility (EMC) Part 4 Testing & Measurement Techniques, Section 3 Radiated, Radio Frequency, Electromagnetic Field Immunity Test
IEC 61000-4-4 Electromagnetic Compatibility (EMC) Part 4 Testing & Measurement Techniques, Section 4 Electrical Fast Transient/Burst Immunity Test
IEC 61000-4-5 Electromagnetic Compatibility (EMC) Part 4 Testing & Measurement Techniques, Section 5 Surge Immunity Test
IEC 61000-4-6 Electromagnetic Compatibility (EMC) Part 4 Testing & Measurement Techniques, Section 6 Immunity to Conducted Disturbances Induced by Radio Frequency Fields
IEC 61000-4-8 First Edition Magnetic Field Immunity
IEC 61000-4-11 First Edition Power Dips and Interruption Immunity
IEC Publication 529 Degrees of Protection Provided by Enclosures (IP Codes)

Software qualification is performed on the system according to specific acceptance criteria, thus confirming the safety and effectiveness of each functional aspect of the Borealis Amplifier.

The "510(k) Substantial Equivalence Decision-Making Process (Detailed)" decision tree (CDRH 510(k) Manual 92-4158) was utilized to make a determination of substantial equivalence. This decision tree is depicted in Section 4 in Figure 4-1 with the decision points relevant to the LabSystem III highlighted in yellow. The answers to the following questions at the indicated decision points in Figure 4-1 lead to a determination of substantial equivalence.

Provided in Section 4 is a document titled "Comparison of the Borealis Amplifier Capabilities and STAMP Amplifier Capabilities. This document provides a comparison of the capabilities of the predicate device to the Borealis Amplifier, subject of this 510(k).

This comparison document was developed to assist in demonstrating the similarities with respect to the capabilities of the two systems. The document contains a tabular comparison of the two systems with the STAMP Amplifier capabilities in the second column. The first column indicates whether or not the corresponding capability exists in the Borealis Amplifier system.

New device is compared to a marketed device
Response: Yes. The Borealis Amplifier, subject of this submission, is compared to the STAMP Amplifier currently marketed by Bard.

Does the new device have the same indication statements?
Response: Yes. The indications for the Borealis Amplifier covered under this Premarket Notification are the same as those of its predicate device. The indications for use for the Bard Electrophysiology LabSysem III Laboratory covered under this Premarket Notification are the same as it's predicate device. Refer to Section 7 for copies of the predicate device labeling.

The Borealis Amplifier is intended to amplify and condition electrocardiographic signals of biologic origin and pressure transducer input, transmitting this information to a host computer (the Bard Electrophysiology LabSystem III Laboratory) that can record and display the information.

The Bard Electrophysiology LabSystem III Laboratory is a computer and software driven data acquisition and analysis tool designed to facilitate the gathering, display, and analysis by a physician, and storage of cardiac electrophysiologic data.

The new device has the same intended use and may be "Substantially Equivalent".

Response: Yes. The Borealis Amplifier, like it's predicate device the STAMP Amplifier, is a real time embedded system designed to amplify and condition electrocardiographic and blood pressure signals of biologic origin for transfer to a host computer (the Bard Electrophysiology LabSystem III Laboratory) that can record and display information.

Does the new device have the same technological characteristics, e.g., design, materials, etc.?

Response: Yes. One of the main reasons for the Premarket Notification Submission of the Borealis Amplifier is due to the near term component obsolescence of many of the components of the predicate device, the STAMP Amplifier. The Borealis Amplifier design is an update of the STAMP Amplifier design that employs available technology that has exactly the same technological characteristics.

Are the descriptive characteristics precise enough to ensure equivalence?

Response: Yes. The Borealis Amplifier uses the same principles for data acquisition and signal conditioning as the STAMP Amplifier using available technology. Methods of communication signal processing represent the current state of the art in keeping with exactly the same indications for use.

The LabSystem III consists of the same basic hardware components and device components. Although there have been upgrades to the various components such as the monitor, keyboard, trackball/mouse, etc. the intended use of the system has not changed.

Please refer to the document titled "Comparison of the Borealis Amplifier Capabilities and the STAMP Amplifier Capabilities" in Section 4. As stated above, this document provides a comparison of the capabilities of the predicate device to the Borealis Amplifier, subject of this 510(k).

Although Bard believes that the descriptive characteristics are precise enough to ensure equivalence, test data is provided to demonstrate that the system meets the specified performance requirements.

Section 3 contains a summary of all testing conducted in support of the Borealis Amplifier. The individual reports are provided in the Appendices in Volume II.

As mentioned above, Volume II contains the Performance Specification Requirement along with the individual reports including Electrical Safety, EMC Emissions Test, the EMC Immunity Test, the System Stress Test Protocol and Report, and the Software Verification and Validation Test Plan and Report.

The testing demonstrates that the Borealis Amplifier meets the established performance requirements.

Based on the comparison document in Section 4 and the testing summarized in Section 3 (reports in Volume II, Appendices) Substantial Equivalence to the predicate device, STAMP Amplifier, has been demonstrated.

Following the decision making process outlined above leads to a "Substantially Equivalent" determination.

Revision History

Revision	Date	Author	Description
1	12/01/04	W. Griffin	Est. Reg. No.
2	12/16/04	W. Griffin	Add EN 60601-1-1 & edits

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

MAY 27 2005

C.R. Bard, Inc.
c/o Ms. Deborah L. Herrington
Manager, Regulatory Affairs
Bard Electrophysiology
55 Technology Drive
Lowell, MA 01851

Re: K050006
Trade Name: Bard Borealis (CLEARSIGN) Amplifier
Regulation Number: 21 CFR 870.2060
Regulation Name: Transducer Signal Amplifier and Conditioner
Regulatory Class: Class II (two)
Product Code: 74 DRQ
Dated: May 12, 2005
Received: May 13, 2005

Dear Ms. Herrington:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K05000 6

Device Name: Bard Borealis (CLEARSIGN) Amplifier

Indications For Use:

The Bard Borealis (CLEARSIGN) Amplifier is intended to amplify and condition electrocardiographic signals of biologic origin and pressure transducer input, transmitting this information to a host computer (the Bard LabSystem III EP Laboratory) that can record and display the information.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K050006