

OCT 2 1998



Belmont Instrument Corporation

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Registered In Accordance with ISO-9001 (Certificate # 041007407)

PREMARKET NOTIFICATION 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS [As Required By 21 CFR 807.92(c)]

Date prepared: June 25, 1998

1. Submitter & Manufacturing Site: Belmont Instrument Corporation
780 Boston Road
Billerica, MA 01821

Establishment Registration Number: 1219702
2. Contact Person: Uraivan P. Labadini, Quality Assurance/Regulatory Affairs Manager

Telephone: (978) 663-0212 Ext. 28 Fax: (978) 663-0214
3. Trade Name: Belmont Portable Balloon Pump, Bard TransAct IABP
4. Common name: Intra-Aortic Balloon Pump Control System
5. Classification name: Component of the Intra-Aortic Balloon Pump (per 21 CFR section 870.3535)
6. Product Code: 74DSP: Intra-Aortic Balloon Pump
Device Class: Class III: Intra-Aortic Balloon Pump
7. Performance Standards:
No performance standards have been officially adopted by the F.D.A.
8. Belmont Instrument Corporation intends to **revise** software used in the Intra-Aortic Balloon Pump (IABP). There are no other changes to the IABP for which a 510(k) was approved in October 1992. The revised software provides a more convenient way for Operators of the pump to set the ECG gain. In particular, the change will accommodate high gain settings by the operator, in which the ECG R-Wave amplitude is set far higher than the triggering threshold. Setting the ECG gain too high can lead to noise affecting triggering. In the existing software, the thresholds for ECG R-Wave detection, pacer spike detection, and noise detection are all fixed

values. In the upgraded version, the R-Wave trigger threshold is scaled to a moving average of prior R-Wave amplitudes with the most recent R-Wave amplitude weighted the most heavily. The pacer detection and noise detection threshold are, in turn, scaled to the new R-Wave threshold.

9. **Brief Description:** The IABP software program has been compiled and linked to run from the system EPROM. In the current system, the thresholds for ECG R-Wave detection, pacer spike detection, and noise detection are all fixed values. In the revised software, the R-Wave trigger threshold is scaled to a moving average of prior R-Wave amplitudes with the most recent R-Wave amplitude weighted the most heavily. The pacer detection and noise detection thresholds are, in turn, scaled to the new R-Wave amplitude.

If the user sets the ECG gain low, the new triggering threshold will be low. If the ECG gain is raised, the new triggering threshold is raised. Triggering threshold is computed by first computing the moving average of R-Wave amplitude. The detection threshold is a fixed fraction of the moving average, where the fraction is higher (0.75) during up to 400ms after the last R-Wave and lower (0.57) during the period after 400ms. For most beats the threshold for ECG triggering is just over 1/2 that of the previous beats.

10. **Intended Use:** The balloon pump is an electromechanical system used to drive intra-aortic balloons. It provides temporary support to the left ventricle via the principle of counterpulsation. The intra-aortic balloon is placed in the descending aorta, just distal to the left subclavian artery. Once the balloon is positioned, the pump is adjusted to trigger in synchrony with the ECG or arterial pressure waveform to ensure that inflation and deflation occur at the appropriate points during the cardiac cycle.
There are no changes to the intended use of the IABP for which a 510(k) was approved in October 1992.
11. **Summary of the technological characteristics of the revised software compared to the current software used in the IABP.**

A. Comparison of Software Specifications:

The original software and the revised software specification are compared side-by-side. There are no changes, other than those pertaining to ECG triggering threshold levels.

B. Software Quality Assurance Plan

The Software Quality Assurance Plan described the software quality assurance requirements to be applied to the software to be used in the Belmont IABP. This document addressed the software quality assurance functions implemented by Belmont Instrument Corp. to conform to FDA requirements contained in the Reviewer Guidance for Computer Controlled Medical Devices. This Software Quality Assurance Plan (SQAP) has been

designed to address the requirements of ANSI/IEEE Standard 730.1-1989 "IEEE Standard for Software Quality Assurance Plans" with regard to the preparation and content of Software Quality Assurance Plans.

C. Search of Existing Devices for Problems relating to Safety and/or Effectiveness:

In this phase, a hazard analysis was performed by analyzing all possible hazardous conditions on the software, system, and device. A computerized literature search was performed encompassing all reported hazards encountered in balloon pumping including problems resulting from the balloon, the control system, user error, insertion problems, or physician error. All problems which relate in any way to the control system were tabulated, including problems due to the balloon and poor insertion, etc., which could be detected by the control system. After tabulating potential hazards of the system, we implemented a series of safety measures to ensure that the machine would stop operation and alarm at all hazards, and that the failure of no one component could cause a serious problem.

12. Summary of Nonclinical Tests and Results

We verify that the revised software performs according to specifications as follow:

- A. The software algorithms are satisfied, quantitatively.
- B. The revised software enables the IABP to trigger effectively over the full specified range of heart rate, 30 - 200 BPM.
- C. The revised software enables IABP to trigger effectively over a wide range of clinical conditions as demonstrated by performance with the American Heart Association ECG Database, and by deliberately synthesizing specific arrhythmias, and ECG morphologies, using ECG Arrhythmia Simulators, and clinical tapes.
- D. The revised software demonstrates improved performance at very high ECG gain setting, and still function properly at low gain, including lower amplitude ECG than is possible with the current (unmodified) software.
- E. The revised software is designed to function in the present Belmont PBP system, with an ECG gain control set by the Operator. The system must therefore, respond quickly and effectively to sudden changes in ECG gain.

Finally, we perform the system testing which is a test of the integrated hardware and software system to ensure that all system requirements are met including:

- i) all safety features function properly,
- ii) the system will stop operation in a safe manner at all identified

conditions which could adversely affect safety or efficacy,
using the "Final Functional Test Procedure, PBP-Q108".

The system passes all applicable tests.

13. Conclusion: We believe that our revised software is substantial equivalent to the current software. The claim of substantial equivalence is based on the following:
 - A. Same intended use - both systems are capable of appropriately trigger balloon inflation and deflation from ECG waveforms, even in the presence of artifacts, pacing spikes, and arrhythmias.
 - B. Both systems alarm, display an alarm message, and stop at all unsafe conditions.
 - C. The differences between the two software do not raise new types of safety or effectiveness questions.
 - D. Our performance tests to support substantial equivalence have demonstrated that the revised software is as safe, as effective, and performs as well as the current software used in the legally marketed device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 2 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Uraiwan P. Labadini
Quality Assurance/Regulatory Affairs Manager
Belmont Instrument Corporation
780 Boston Road
Billerica, MA 01821

Re: K982538
Intra-Aortic Balloon Pump (IABP) Software
Regulatory Class: III
Product Code: 74 DSP
Dated: September 3, 1998
Received: September 4, 1998

Dear Mr. Labadini:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

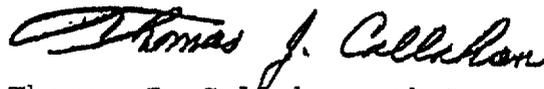
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) number: K982538

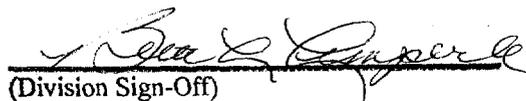
Device Name: Software to be used in the IABP

Indications For Use:

There are no changes to the intended use of the IABP for which a 510(k) was approved in October 1992 [510(k) number K915580]. The balloon pump is an electromechanical system used to drive intra-aortic balloons. It provides temporary support to the left ventricle via the principle of counterpulsation. The intra-aortic balloon is placed in the descending aorta, just distal to the left subclavian artery. Once the balloon is positioned, the pump is adjusted to trigger in synchrony with the ECG or arterial pressure waveform to ensure that inflation and deflation occur at the appropriate points during the cardiac cycle.

(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, Respiratory,
and Neurological Devices

510(k) Number K982538

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use