

JAN - 6 2000

K983866

Attachment 5



# Belmont Instrument Corporation

780 Boston Road, Billerica, MA 01821 (978)663-0212, Fax: (978)663-0214

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

## Premarket Notification 510(k) Summary

[As Required By 21 CFR 807.92(c)]

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 Model NGPBP Intra-Aortic Balloon Pump
4. Common name: Intra-aortic Balloon Pump
5. Classification name: Intra-aortic Balloon Pump Control System.
6. Product Code: 74DSP  
Device Class: Classified as a Class III device per Federal Register July, 1978.
7. The Belmont Model NGPBP IABP is similar in design, function, user interface, principles of operation, and technology to the Belmont Model PBP Intra-Aortic Balloon Pump, which has been commercially available since 1992 as Bard TransAct H-8000, and was the subject of Premarket Notification #K915580 submitted in November 1991.
8. Brief Description: The Belmont NGPBP System is a light and compact portable system, designed to facilitate balloon pumping at the patient's bedside. The portable balloon pump is a reliable, safe, and effective system designed especially for ease of operation and transportation.

The Belmont NGPBP is made up of eight major functional elements:

- I. Operator Interface
- ii. Signal Acquisition and Display
- iii. Triggering and Assist Timing
- iv. Pneumatics: Pump Drive System
- v. Pneumatics: Volume Control System
- vi. Pneumatics: Shuttle Gas System
- vii. System surveillance
- viii. Power System

9. **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.
10. **Summary of the technological characteristics of the Belmont PBP compared to the Belmont NGPBP.**

The two systems perform the identical function, both contain the identical eight major function elements as described above. This Belmont NGPBP will be differentiated from the existing Belmont PBP, by reduced operator input (i.e., automated operation) and having reduced size and weight. It will also feature improved ergonomics and more intuitive user interface.

- a. **Operator Interface:** The Belmont NGPBP provides for automatic ECG amplitude scaling for triggering, automatic gas surveillance, same as the Belmont PBP. However, the Belmont NGPBP provides two modes of operation - an automatic mode and a manual mode. In automatic mode, the system will operate the pump with minimum user input. Once the automatic mode is chosen, the system will analyze all three ECG leads, ECG monitor signal (if connected), and arterial pressure (AP) signal (both transducer or monitor, if connected) and choose the best available signal for triggering, and the system will determine the optimal timing of inflation and deflation based on an analysis of the AP, BP, and ECG waveforms.
- b. **Signal Acquisition and display:** Both systems utilize ECG signals from skin leads via a patient cable and arterial pressure signals from a direct transducer which is connected to an arterial cannula or the central lumen of the intra-aortic balloon. Both systems also utilize amplified signals from an external monitor.
- Both systems display 3 signals: the ECG, arterial pressure, and balloon gas pressure waveforms. Both systems also display digital values of the AP and BP signals, and heart rate. Both systems provide alarm messages in case of operational difficulties with the balloon/catheter or with the system and also status messages to indicate AC/DC status, battery charge, and helium gas status
- c. **Triggering and Assist Timing:** Both systems detect the ECG R-Wave, the V-Pacemaker spike or the upstroke of systolic arterial pressure and use for triggering.

In the manual mode of operation for both pumps, the operator selects from the following modes: a) ECG, b) Arterial pressure trigger, and c) Internal (asynchronous) trigger. The operator sets inflation timing, and deflation timing. In the automatic mode (for Belmont NGPBP only), the Trigger Mode and Timing

settings are determined by the system by analyzing the ECG and arterial pressure waveforms, no user action is required. During total bypass when the Internal Trigger mode is to be utilized, the Operator Directed Mode will be activated. ✕

- d. Pneumatics: Pump Drive System: Same technology for Belmont PBP and Belmont NGPBP.

For both systems:

Balloon inflation and deflation is actuated by the Pump Drive System, which activates the Volume Control System which meters the correct volume displacement to inflate the balloon properly, using helium shuttle gas from the Shuttle Gas System. The Pump Drive System consists of a compressor/vacuum pump, 2 ballast tanks with air pressure transducers to monitor pressure and vacuum, and pulse valves which control application of air pressure or vacuum to the Volume Control System and provide for relief of pressure to make the vacuum cycle more efficient. A third pressure transducer monitors pressure on volume control side of the valves.

- e. Pneumatics: Volume Control System: Same technology for Belmont PBP and Belmont NGPBP.

For both systems:

The Volume Control System consists of the Adjustable Volume Limiter (AVL), which isolates air pressure and vacuum from the balloon and controls balloon inflation volume, two valves for filling and venting helium gas from the Shuttle Gas System, and a pressure transducer for monitoring shuttle gas pressure.

- f. Pneumatics: Shuttle Gas System: Same technology for Belmont PBP and Belmont NGPBP.

For both systems:

The Shuttle Gas System delivers helium gas to the AVL fill valve at low pressure. The helium source is a disposable helium cylinder, which is pressurized to greater than 2000 psi. The system contains a piercing mechanism for puncturing the cylinder, and 2 regulators to reduce the helium pressure to a safe level. The new system also contains a pressure transducer for reading helium source pressure, which is done by a pressure switch in the old system, and a blow off valve as a safety measure. } ✕

- g. Surveillance System: Same technology for Belmont PBP and Belmont NGPBP.

For both systems:

The Gas Surveillance System uses the helium pressure, air drive pressure, and vacuum to determine unsafe balloon and internal conditions including balloon

disconnection, overfilling, gas leakage, kinked catheter, and slow deflation. Internal Self Checks determine system malfunctions, and indicate battery charge and helium status. While pumping, all surveillance systems are active. An override mode allows operation without a balloon and disables the balloon disconnection and gas leakage alarms.

The Surveillance system is used to activate alarms at all unsafe conditions. At an alarm condition, an audible tone is activated, the balloon is deflated, with no further inflation until the source/cause of the alarm is eliminated. To aid the Operator, an alarm message is displayed on the monitor screen indicating the source of the problem. When the source of the problem is eliminated, most alarm conditions require the user to restart pumping. In two conditions, loss of trigger and noisy ECG signal, pumping restarts automatically when problem is eliminated. The recorder printout will show the problem and indicated alarm status, if the recorder is activated.

h. Power System

Both systems obtain its power directly from the wall receptacle, during AC power operation. When the AC power is discontinued, full operation of the system is automatically transferred to the internal battery if it is adequately charged. The rechargeable battery provides power to the unit during transportation.

11. Summary of Nonclinical Tests and Results

In order to verify performance of the Belmont NGPBP in support of substantial equivalence, the following tests were carried out:

a. Inflation and Deflation Tests with Commercially available Balloons at 60 and 125 BPM. The ability of the Belmont NGPBP to fully inflate and deflate all commercially available balloons. Balloons from all of the known manufacturers: Bard Cardiac Assist Products, Arrow International, Bard (St. Jude Medical), and Datascope Corporation balloons were tested with the static pressure 90 mm Hg and heart rates of 60 and 125 BPM, including balloons having nominal volumes of 30, 34, 40, 50cc. The Belmont NGPBP compared well with the Belmont PBP.

b. Triggering and Timing under a Variety of Clinical Conditions

The ability of the Belmont NGPBP to appropriately trigger balloon inflation and deflation from ECG waveform, even in the presence of artifacts, pacing spikes, and arrhythmias with variable heart rate was tested.

The Belmont Model NGPBP, same as the Belmont PBP, accurately and properly synchronized the inflate/deflate cycle of the balloon with the patient's heart for a variety of normal and abnormal rhythms with variable heart rate. If the unit could not track the ECG and trigger appropriately in the presence of

artifact, and interference, the balloon remained deflated and alarm was activated.

- i. Belmont Model NGPBP compared well with the current IABP. Each of the pumps was able to trigger properly from ECGs with normal sinus rhythms with heart rates of 30-200 BPM.
- ii. Each of the pumps responded by deflating during PVCs. The NGPBP and the current IABP pumped acceptably during Atrial Fibrillation (hold inflation until the next R-wave). When the pumps were tested using Ventricular Tachycardia, and erratic rate with Ventricular Fibrillation, and A-Paced, they both triggered properly.

Each of the pumps responded well to the baseline shift, baseline noises, wide QRS, and tall T-wave.

12. Conclusion: The Belmont NGPBP is substantially equivalent to the Belmont PBP which received 510(k) approval in October 1992. Both system has the same intended use, are capable of appropriate trigger balloon inflation and deflation from arterial pressure waveform and ECG waveforms, even in the presence of artifacts, pacing spikes, and arrhythmias. Both systems alarm, display alarm message, and stop at all unsafe conditions.



JAN - 6 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K983866  
Trade Name: Belmont Model AUTO-CAT Intra-Aortic Balloon Pump  
Regulatory Class: III  
Product Code: DSP  
Dated: October 8, 1999  
Received: October 15, 1999

Dear Ms. 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 (Premarket 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

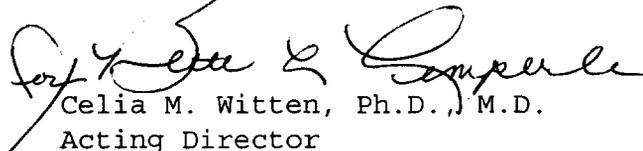
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you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4586. 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" (21CFR 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,



Celia M. Witten, Ph.D., M.D.

Acting Director

Division of Cardiovascular,

Respiratory and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) number:           K983866          

Device Name: Belmont NGIABP

Indications For 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.

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\_\_\_\_\_ Concurrence of CDRH, Office of Device Evaluation (ODE) \_\_\_\_\_



(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number           K983866          

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_