



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 2, 2015

Belmont Instrument Corporation
Uraiwan P. Labadini
780 Boston Road
Billerica, Massachusetts 01821

Re: K152208

Trade/Device Name: Belmont® Hyperthermia Pump
Regulation Number: N/A
Regulation Name: N/A
Regulatory Class: Unclassified
Product Code: LGZ
Dated: August 6, 2015
Received: August 7 2015

Dear Mr. Labadini:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152208

Device Name

The Belmont Hyperthermia Pump

Indications for Use (Describe)

The intended use of the Belmont Hyperthermia Pump is to raise the temperature of the thoracic or peritoneal cavity to the desired target temperature by continuously lavaging the cavity with circulating warmed sterile solution, according to a protocol to be selected by the physician.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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

Special 510(k) No. K152208

Submitter Name and Address: Belmont Instrument Corporation
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Billerica, MA 01821

Contact Person: Uraiwan P. Labadini
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Date Summary Prepared: September 2, 2015

Trade/Proprietary Name of Device: The Belmont[®] Hyperthermia Pump

Regulatory Class: Unclassified

Product Code: LGZ (Warmer, Thermal, Infusion Fluid)

Legally Marketed Device Under Which Substantial Equivalence is Claimed: The Belmont[®] Hyperthermia Pump cleared for market entry originally under 510(k) K070654, 1st modification cleared under 510(k) K090089.

Device Description: The Belmont[®] Hyperthermia Pump combines advanced microprocessor technology with an efficient mechanical system to provide a high speed, simple and safe system for rapid perfusion of warmed fluid. It can raise the temperature of the thoracic or peritoneal cavity to the desired target temperature by continuously lavaging the cavity with circulating warmed sterile solution, according to a protocol to be selected by the physician.

The system monitors fluid temperature, patient temperature, line pressure, and air in the fluid path to ensure safe operation and alarms at all unsafe conditions. A hardware override circuit prevents unsafe operation in case of system computer failure. A touch screen displays flow rate, total fluid pumped, output fluid temperature, target temperature, patient temperature, line pressure, alarm and status messages and proper procedures

to proceed safely after an alarm situation.

A battery backup allows for mobile transport of the patient and system. During battery operation, fluid warming is disabled while pump operation and safety monitoring remain active.

Intended Use:

The intended use of the Belmont[®] Hyperthermia Pump is to raise the temperature of the thoracic or peritoneal cavity to the desired target temperature by continuously lavaging the cavity with circulating warmed sterile solution, according to a protocol to be selected by the physician.

Comparison of Technological Characteristics of the Device vs. the Legally Marketed Device:

Belmont Instrument Corporation is claiming substantial equivalence of the Belmont[®] Hyperthermia Pump, to our Belmont[®] Hyperthermia Pump which was originally cleared to market under 510(k) K070654 on June 8, 2007, and to the Belmont[®] Hyperthermia Pump 1000 ml/min flow rate was cleared to market under 510(k) K090089 on February 12, 2009.

Specific Modifications being reviewed in this submission:

The Belmont[®] Hyperthermia Pump was a modification of the Rapid Infuser which has been in clinical use for more than 15 years; consequently a component used in the system had become obsolete and hard to obtain. Therefore, the system hardware (chip replacement), and software (to correspond with the chip changes) have been upgraded. At the same time, we are using a brighter monochromatic display with a higher contrast LCD to improve visibility. We have performed a rigorous validation to ensure that these updates are backward compatible with our existing system and no major functions have been altered.

Brief Discussion of Nonclinical Tests and their Results Submitted in the Application:

In order to verify performance of the Belmont[®] Hyperthermia Pump in support of substantial equivalence, the following tests were carried out:

- a. The ability of the system to pump fluids accurately over the full range of flow rate and operating conditions including different input fluid temperatures, different back pressure levels, and change in ambient temperature.

*Brief Discussion of Nonclinical Tests and their Results Submitted in the Application: **Cont'd***

- b. The ability of the system to warm cold fluids to the user set temperature over the full range of flow rate and operating conditions.
- c. The ability of the system to detect and alarm at unsafe or ineffective operating conditions including over temperature, the unsafe high line pressure condition, out of fluid, air in the line and at any of several internal fault conditions.
- d. We performed risk assessment and performed the verification and validation tests to ensure that these risks were mitigated and method of controls were implemented correctly.
- e. We validated each algorithm for each function element in the software specification using an approved procedure. We also performed extensive testing for the entire system with software in place to test both the hardware and software functions to ensure that all system requirements are met.
- f. Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance.
- g. Medical Electrical Equipment Collateral Standard: Electromagnetic Compatibility

The Belmont® Hyperthermia Pump performed within specifications in all of the above tests.

Conclusion:

The Belmont® Hyperthermia Pump is substantially equivalent to the Belmont® current product which received 510(k) approval at various times. Both systems are capable of high infusion flow rates, while maintaining infusate at user-set temperature, and both systems are suitable for use with sterile solutions. Both systems monitor flow rate, temperature, line pressure, and the presence of air at the input line or within the system, and alarm and stop the system at all unsafe conditions.

The tests demonstrate that the Belmont® Hyperthermia Pump is substantial equivalent and performs as well as the legally marketed device.