K141654

JUL 18 2014

Belmont Instrument Corporation

Established 1980

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

Submitter Name and Address:	Belmont Instrument Corporation 780 Boston Road Billerica, MA 01821
Contact Person:	Uraiwan P. Labadini Quality Assurance/Regulatory Affairs Manager Telephone: (508) 663-0212 Ext. 128 Fax: (508) 663-0214 Email address: ulabadini@belmontinstrument.com
Date Summary Prepared:	July 17, 2014
Trade/Proprietary Name of Device:	The Belmont® Rapid Infuser, RI2
Common Name:	Infusion Pump
Classification Name:	Infusion Pump, 21 CFR 880.5725 Warmer, Thermal, Infusion Fluid
Legally Marketed Device Under Which Substantial Equivalence is Claimed:	The Belmont® Rapid Infuser cleared for market entry originally under 510(k) K972284, 1st modification cleared under 510(k) K032674, and 2nd modification cleared under 510(k) K091855.
Device Description:	The Belmont® Rapid Infuser, RI2, (same as the existing Rapid Infuser) combines advanced microprocessor technology with an efficient mechanical system to provide a high speed, simple and safe system for rapid infusion of warmed fluid. The Rapid Infuser infuses blood, replacement IV fluids or irrigation fluids warmed to physiologic temperature at user-set rates from 10 to 1000 milliliters per minute (ml/min). A low infusion rate at 2.5 ml/min (150 ml/hr) is also available without heating. The system monitors 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 infused, 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 Belmont® Rapid Infuser, RI2, is for use in high blood loss surgical procedures, trauma and any situation where rapid replacement of warmed blood or replacement fluid at 10 - 1000 ml/min is required. It can also be used to deliver irrigation fluids at rates up to 1000 ml/min.

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

Belmont Instrument Corporation is claiming substantial equivalence of the Belmont® Rapid Infuser, RI2, to the Belmont® Rapid Infuser which was originally cleared to market under 510(k) K972284 on November 13, 1997, and to the Belmont® Rapid Infuser 750 ml/min flow rate was cleared to market under 510(k) K032674 on September 16, 2003, and to the Belmont® Rapid Infuser 1000 ml/min flow rate was cleared to market under 510(k) K091855 on July 1, 2009.

Specific Modifications being reviewed in this submission:

The Belmont® Rapid Infuser has been in clinical use for more than 14 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® Rapid Infuser, RI2, 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, change in ambient temperature, and changes in fluid viscosity including that of crystalloid solution and packed red blood cells.

b. The ability of the system to warm cold fluids to physiological 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 regarding the keypad, i.e., key stick, key bounce/failure, operator error by pressing the wrong key, unintentional activation of the keypad, and fluid spillage on the keypad. We performed the verification and validation tests to ensure that these risks were mitigated and method of controls were implemented correctly.

e. We generated a software life cycle in according to the IEC 62304. 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® Rapid Infuser, RI2, performed within specifications in all of the above tests.

Conclusion:

The Belmont® Rapid Infuser, RI2, is substantially equivalent to the Belmont® Rapid Infuser which received 510(k) approval at various times. Both systems are capable of high infusion flow rates, while maintaining infusate at physiological temperature, and both systems are suitable for use with blood products. 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® Rapid Infuser, RI2, is substantial equivalent and performs as well as the legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 18, 2014

Belmont Instrument Corporation
Uraiwan Labadini
Quality Assurance / Regulatory Affairs Manager
780 Boston Road
Billerica, Massachusetts 01821

Re: K141654

Trade/Device Name: Belmont® Rapid Infuser, RI2
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: FRN, LGZ
Dated: June 18, 2014
Received: June 20, 2014

Dear Ms. 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, M.S.
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): K141654

Device Name: The Belmont® Rapid Infuser, RI2

Indications for Use:

A. Infusion of crystalloid, colloid, or blood product, including packed red blood cells, as volume replacement for patients suffering from blood loss due to trauma or surgery.

B. Infusion of warmed fluid to rewarm patients after surgery or for hypothermia.

C. Infusion of warmed fluid for irrigation in urology procedures.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary E. Brooks -A
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