December 23, 2024

Belmont Medical Technologies
Lida Reed
Director Quality Assurance and Regulatory Affairs
780 Boston Road
Billerica, Massachusetts 01821

Re: K242735
Trade/Device Name: Belmont Rapid Infuser, RI-2 (Rapid Infuser RI-2, 1000 ml/min); Belmont Rapid Infuser, RI-2 (Rapid Infuser RI-2, 750 ml/min)
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: FRN, LGZ
Dated: November 21, 2024
Received: November 21, 2024

Dear Lida Reed:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jake K. Lindstrom -S

Jake Lindstrom, Ph.D
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242735

Device Name
Belmont Rapid Infuser, RI-2 (Rapid Infuser RI-2, 1000 ml/min)
Belmont Rapid Infuser, RI-2 (Rapid Infuser RI-2, 750 ml/min)

Indications for Use *(Describe)*
The Belmont Rapid Infuser RI-2 is designed to be used in general operation in hospital or alternative care environments to provide warmed blood and fluids to any patients ≥ 10 kg requiring warmed infusion from 2.5 mL/min to 1000 mL/min.
- 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.
- Infusion of warmed fluid to rewarm patients after surgery or for hypothermia.
- Infusion of warmed fluid for irrigation in urology procedures.

The 3.0L reservoir is an optional accessory for use in adults only.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Date: December 17, 2024

Company: Belmont Medical Technologies
780 Boston Road
Billerica, MA 01821

Official Contact: Lida Reed
Director Quality Assurance and Regulatory Affairs
Phone: 978.696.9245
Email: lreed@belmontmedtech.com

Proprietary or Trade Name: Belmont® Rapid Infuser, RI-2

Common/Usual Name: Infusion Pump

Classification Name: 21 CFR 880.5725, Class II
Classification Product Code: FRN
Subsequent Product Code: LGZ

Predicate Device: K141654: The Belmont Rapid Infuser
This predicate has not been subject to a design-related recall.

Device Description:
The Belmont® Rapid Infuser, RI-2 combines advanced microprocessor technology with an efficient mechanical system to provide a high speed, simple and safe system for rapid infusion of warmed fluids. 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). Low infusion rates of 2.5 mL/min (150 mL/hr) and 5.0 mL/min (300 mL/hr) are also available to keep the venous line open.

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 of the infusate, 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 limited to 50mL/min and safety monitoring remain active.

Indications for Use:
The Belmont Rapid Infuser RI-2 is designed to be used in general operation in hospital or alternative care environments to provide warmed blood and fluids to any patients ≥ 10 kg requiring warmed infusion from 2.5 mL/min to 1000 mL/min.

- 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.
- Infusion of warmed fluid to rewarm patients after surgery or for hypothermia.
- Infusion of warmed fluid for irrigation in urology procedures.

The 3.0L reservoir is an optional accessory for use in adults only.

Contraindications:

- The system should not be used to warm platelets, cryoprecipitates, granulocyte suspensions or unprocessed / non-anti-coagulated blood products.
- This system is not intended for drug administration.
- Calcium containing solutions (ex. Lactated Ringer's solution), dextrose in water, and hypotonic sodium chloride solutions should not be added to blood components.

Substantial Equivalence:
The Belmont® Rapid Infuser RI-2 is substantially equivalent to the predicate device, the Belmont® Rapid Infuser RI-2 (510(k) K141654). The table below presents the similarities and differences between the products for substantial equivalence purposes. The differences between the subject device and the predicate device do not raise any new issues of safety and effectiveness. Performance data are available to support substantial equivalence.

Element of Comparison	Predicate Device: Belmont® Rapid Infuser, RI-2 [510(k) K141654]	Subject Device: Modified Belmont® Rapid Infuser, RI-2	Substantial Equivalence
1.0 General:			
• Common/ Classification	Infusion Pump/ Pump, Infusion Warmer Thermal Infusion Fluid Warmer	Infusion Pump/ Pump, Infusion Warmer Thermal Infusion Fluid Warmer	**SAME**
• Regulation Number	21 CFR 880.5725	21 CFR 880.5725	**SAME**
• FDA Product Codes	FRN LGZ	FRN LGZ	**SAME**
• Trade name	Rapid Infuser	Rapid Infuser	**SAME**
• Model Number	RI2	RI2	**SAME**

Element of Comparison	Predicate Device: Belmont® Rapid Infuser, RI-2 [510(k) K141654]	Subject Device: Modified Belmont® Rapid Infuser, RI-2	Substantial Equivalence
• Indications for use	▪ 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, ▪ Infusion of warmed fluid to rewarm patients after surgery or for hyperthermia, and ▪ Infusion of warmed fluid for irrigation in urology procedures.	The Belmont Rapid Infuser RI-2 is designed to be used in general operation in hospital or alternative care environments to provide warmed blood and fluids to any patients ≥ 10 kg requiring warmed infusion from 2.5 mL/min to 1000 mL/min. ▪ 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, ▪ Infusion of warmed fluid to rewarm patients after surgery or for hyperthermia, and ▪ Infusion of warmed fluid for irrigation in urology procedures. The 3.0L reservoir is an optional accessory for use in adults only.	**SIMILAR** The subject device clarifies that the device is for use in patients ≥ 10 kg. This clarification does not impact the intended use which is rapid infusion of warmed blood, blood products and fluids.
• Device description	High speed infusion pump with fluid warming.	High speed infusion pump with fluid warming.	**SAME**
• Infusate	Blood, blood product, crystalloid and colloid solutions.	Blood, blood product, crystalloid and colloid solutions.	**SAME**
2.0 Fluid Infusion (Pump) Characteristics:			
• Available flow rates	2.5, 5.0, 10 to 1000 mL/min	2.5, 5.0, 10 to 1000 mL/min	**SAME**

Element of Comparison	Predicate Device: Belmont® Rapid Infuser, RI-2 [510(k) K141654]	Subject Device: Modified Belmont® Rapid Infuser, RI-2	Substantial Equivalence
• Flow rate accuracy	± 10% from 20 – 1000 mL/min ± 25% for 2.5, 5.0, 10 mL/min	± 10% from 20 – 1000 mL/min ± 25% for 2.5, 5.0, 10 mL/min	**SAME**
• Type of Fluid Pump	Roller type peristaltic pump	Roller type peristaltic pump	**SAME**
• Digital readout of flow rate	Yes	Yes	**SAME**
• Automatic reduction of pump speed, if required, to maintain user-set line pressure limit	Yes	Yes	**SAME**
• Digital setting of speed by user from front panel	Yes	Yes	**SAME**
• Control and maintain pump speed with variable pressure head	Yes	Yes	**SAME**
• Maximum pressure at which set flow maintained (mmHg)	300 mmHg standard. Can be changed by the Operator to 100 or up to 300 mmHg, in 50 mmHg increments.	300 mmHg standard. Can be changed by the Operator to 100 or up to 300 mmHg, in 50 mmHg increments.	**SAME**
• Display total volume infused	Yes	Yes	**SAME**
• Continuous infuse and fixed bolus volume modes (fill until a fixed volume of fluid is delivered)	Yes	Yes	**SAME**
• Monitor pump speed and alarm if speed not equal to setting.	Yes	Yes	**SAME**

Element of Comparison	Predicate Device: Belmont® Rapid Infuser, RI-2 [510(k) K141654]	Subject Device: Modified Belmont® Rapid Infuser, RI-2	Substantial Equivalence
• Alternate fluid path	Yes, recirculate mode, controlled by diversion valve, routes fluid back to system reservoir to purge any air in the main fluid circuit back into the reservoir to be vented.	Yes, recirculate mode, controlled by diversion valve, routes fluid back to system reservoir to purge any air in the main fluid circuit back into the reservoir to be vented.	**SAME**
3.0 Warming Characteristics:			
• Steady state fluid output temperature	37.5ºC at high flow, 60 mL/min and higher; and 39ºC at low flow, less than 60 mL/min (Higher temperature at low flow to compensate for cooling in patient line.)	37.5ºC at high flow, 60 mL/min and higher; and 39ºC at low flow, less than 60 mL/min (Higher temperature at low flow to compensate for cooling in patient line.)	**SAME**
• High temperature alarm condition (Infusate Over Temp)	Output temperature >42ºC for 20 mL of fluid pumped or fluid temperature >45ºC for 0.25 seconds.	Output temperature >42ºC for 20 mL of fluid pumped or fluid temperature >45ºC for 0.25 seconds.	**SAME**
• Maximum speed for steady state 37ºC	1000 mL/min	1000 mL/min	**SAME**
• Measure and display output temperature of infusate	Yes	Yes	**SAME**
• Heat exchanger type	Inductively heated stainless steel annular rings	Inductively heated stainless steel annular rings	**SAME**
• Method of temperature control	Measure input and output temperatures from the temperature sensors, compute required power to the heat exchanger to maintain the targeted temperature. Redundant check using flow rate, input power, input temperature.	Measure input and output temperatures from the temperature sensors, compute required power to the heat exchanger to maintain the targeted temperature. Redundant check using flow rate, input power, input temperature.	**SAME**
4.0 Alarms and System Surveillance:			

Element of Comparison	Predicate Device: Belmont® Rapid Infuser, RI-2 [510(k) K141654]	Subject Device: Modified Belmont® Rapid Infuser, RI-2	Substantial Equivalence
Air detection			
• Air detection at input to machine to detect empty reservoir	Yes	Yes	**SAME**
• Redundant in-line air bubble detection near output	Yes	Yes	**SAME**
• Method to eliminate air from system, without disassembly	Yes	Yes	**SAME**
• Type of Air Bubble detector	Ultrasonic	Ultrasonic	**SAME**
• Automatic Air Elimination while pumping	Yes, via “recirculation” mode	Yes, via “recirculation” mode	**SAME**

Element of Comparison	Predicate Device: Belmont® Rapid Infuser, RI-2 [510(k) K141654]	Subject Device: Modified Belmont® Rapid Infuser, RI-2	Substantial Equivalence
Line Pressure monitoring			
• Monitor & Display line pressure	Yes	Yes	**SAME**
• Pressure limit	300 mmHg, standard. User can adjust during setup.	300 mmHg, standard. User can adjust during setup.	**SAME**
• Automatic flow rate control of pump to maintain line pressure below pressure limit	Yes	Yes	**SAME**
• Message to Operator when flow rate is pressure limited	Yes	Yes	**SAME**
• Alarm at high pressure	Yes, at 400 mmHg	Yes, at 400 mmHg	**SAME**
• Alarm if pump stops due to pressure limit	Yes	Yes	**SAME**
• Alarm if pressure ramps too quickly	Yes	Yes	**SAME**
• Time to occlusion alarm	Immediate	Immediate	**SAME**
Temperature Monitoring			
• High temperature alarm: stop pumping, heating, display message	Yes	Yes	**SAME**
• Display true output fluid temperature	Yes	Yes	**SAME**

Element of Comparison	Predicate Device: Belmont® Rapid Infuser, RI-2 [510(k) K141654]	Subject Device: Modified Belmont® Rapid Infuser, RI-2	Substantial Equivalence
System failure surveillance			
• Set-up problem alarms	System door open, heat exchanger not in place	System door open, heat exchanger not in place	**SAME**
• Automatic system check of Air detectors	At beginning of each set-up	At beginning of each set-up	**SAME**
• Fluid out alarm	Yes	Yes	**SAME**
• Missing disposable alarm	Yes	Yes	**SAME**
• Low Battery alarm	Yes	Yes	**SAME**
• Monitor pump speed during operation (“Pump Fault” alarm)	Yes, via digital encoder on shaft of pump motor	Yes, via digital encoder on shaft of pump motor	**SAME**
• Recirc/Infuse Valve failure alarm	Yes	Yes	**SAME**
• Hardware Sense Computer Failure and Stop Pump and Heat	Yes	Yes	**SAME**
• System response to alarm condition for pressure over limit, air detected, pump fault, system setup problem.	Stop pump, close diversion valve (revert to recirculate), stop heat	Stop pump, close diversion valve (revert to recirculate), stop heat	**SAME**
• Audible Alarm with message at each condition	Yes	Yes	**SAME**
• Operator can silence alarm tone, as alarm is serviced	Yes	Yes	**SAME**

Element of Comparison	Predicate Device: Belmont® Rapid Infuser, RI-2 [510(k) K141654]	Subject Device: Modified Belmont® Rapid Infuser, RI-2	Substantial Equivalence
5.0 Operator Interface:			
Parameters monitored and displayed continuously.	Flow Rate, Volume Infused, Output temperature, Line Pressure.	Flow Rate, Volume Infused, Output temperature, Line Pressure.	**SAME**
Fluid infusion rate control at front panel with digital readout.	Yes	Yes	**SAME**
Fixed volume infusion (bolus) with monitor of bolus volume.	Yes, bolus volume can be set between 100 to 1000 mL and can be changed to intermediate values of 200, 400 and 500 by pressing the BOLUS button, or in the system service/calibration routine.	Yes, bolus volume can be set between 100 to 1000 mL and can be changed to intermediate values of 200, 400 and 500 by pressing the BOLUS button, or in the system service/calibration routine.	**SAME**
Operating modes	Load disposable Prime (Automatic) Patient Line Prime Infuse Bolus Infuse Recirculate	Load disposable Prime (Automatic) Patient Line Prime Infuse Bolus Infuse Recirculate	**SAME**
Readout	High contrast display using an electroluminescent display with extremely wide viewing angle	High contrast display using an electroluminescent display with extremely wide viewing angle	**SAME**
Languages selectable from front panel	Multiple language selection available	Multiple language selection available	**SAME**
6.0 Operating Environment Requirements:			
Operating temperature	10º to 32ºC	10º to 32ºC	**SAME**
Storage temperature	-15º to 40ºC	-15º to 40ºC	**SAME**
Relative humidity	10% to 90% non-condensing	10% to 90% non-condensing	**SAME**

Element of Comparison	Predicate Device: Belmont® Rapid Infuser, RI-2 [510(k) K141654]	Subject Device: Modified Belmont® Rapid Infuser, RI-2	Substantial Equivalence
Ingress protection	IPX2 per IEC 60529 as required by IEC 60601-1	Overall device is IPX2 with IPX6 where the power cord is connected to the device per IEC 60529 as required by IEC 60601-1	**SIMILAR** Subject device confirmed to have higher ingress protection where the power cord is connected to the device, with all applicable predetermined acceptance criteria met.
7.0 Battery Operation, Transport, Physical Characteristics, Power Consumption:			
Battery Operation for Pump, Alarms, with heat disabled	Yes	Yes	**SAME**
Battery Operation with heat (warming)	No warming in battery mode	No warming in battery mode	**SAME**
Battery running time	30 minutes @ 50 mL/min	30 minutes @ 50 mL/min	**SAME**
Transport	Mounts to IV pole	Mounts to IV pole	**SAME**
Dimensions	13.5" x 7.5" x 12" (34 cm x 19 cm x 31 cm) weight: app. 26 lb. (12 kg)	13.5" x 7.5" x 12" (34 cm x 19 cm x 31 cm) weight: app. 26 lb. (12 kg)	**SAME**
Electrical Safety	Meets UL 60601-1, EN 60601-1 (2005, 3rd edition), CAN/CSA C22.2 No. 60601.1 (2008)	Meets ANSI/AAMI ES60601-1:2005/A1:2012	**SIMILAR** Subject device confirmed to comply with current FDA recognized version of standard, with all applicable predetermined acceptance criteria met.
Electromagnetic Compatibility	Meets EN 60601-1-2 (2007) and IEC 60601-1-2 (2007)	Meets IEC 60601-1-2:2020	**SIMILAR** Subject device confirmed to comply with current FDA recognized version of standard, with all applicable predetermined acceptance criteria met.
Power Consumption	1440 watts	1440 watts	**SAME**
8.0 Disposable Set:			

Element of Comparison	Predicate Device: Belmont® Rapid Infuser, RI-2 [510(k) K141654]	Subject Device: Modified Belmont® Rapid Infuser, RI-2	Substantial Equivalence
Sterile Fluid Path	Preconnected system with sterile, non-pyrogenic fluid path.	Preconnected system with sterile, non-pyrogenic fluid path.	**SAME**
Sterilization	Ethylene Oxide	Ethylene Oxide	**SAME**
Biocompatibility including Hemocompatibility	Meets ISO 10993-1:1994 *(Note: Data submitted with 510(k) K972284)*	Meets ISO 10993-1:2018 Biocompatibility including hemocompatibility conducted on current disposable set with all predetermined acceptance criteria met.	**SIMILAR** Subject device confirmed to comply with current FDA recognized version of standard and FDA Guidance document regarding use of ISO 10993-1, with all applicable predetermined acceptance criteria met.

From the comparison form above, the subject device and predicate device have the same intended use, are both prescription use, and have the same operating principle and method of warming and infusion. The differences in the devices do not raise questions of safety or effectiveness.

Non-clinical performance testing:

Biocompatibility / Materials –
Biocompatibility testing was conducted in accordance with FDA guidance, *Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"*. Testing of the patient-contacting parts of the Belmont® Rapid Infuser RI-2 demonstrates an appropriate biocompatibility profile for the device.

Electrical Safety:
Electrical safety and electromagnetic compatibility testing were conducted in accordance with IEC 60601-1:2005 Ed.3+A1:2012 and IEC 60601-1-2:2020 Ed.4.1 to demonstrate the basic safety, essential performance and emissions and immunity characteristics of the device. The testing demonstrated the appropriate electrical safety and electromagnetic compatibility profile for the device.

Software Verification and Validation Testing
Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software for this device was considered as a "moderate" level of concern.

Bench / Performance Testing –
Comparative performance testing included:

- Verification testing of product requirements
- IPX Water Intrusion testing in conformity with IEC 60529

- Testing for basic safety and essential performance in conformity with IEC 60601-1
- Testing for electromagnetic disturbances in conformity with IEC 60601-1-2
- Testing for alarm systems in conformity with IEC 60601-1-8
- Software validation in conformity with IEC 62304
- Testing for biocompatibility in conformity with FDA Guidance “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process’”

The results demonstrated that the device performance was met and was substantially equivalent to the predicate device.

Substantial Equivalence Conclusion
The performance testing demonstrates that the subject device is substantially equivalent to the predicate device.