K121198

510(k) Summary
Page 1 of 7
18-Apr-2012

JUL 12 2012

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Tel - (0043)1979210515
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Proprietary or Trade Name: BW685 and BW685S

Common/Usual Name: Fluid Warmer

Classification Name: Warmer, thermal, infusion fluid

Predicate Devices: Biegler BW385L K954769

Device Description:
The BW685 and BW685S are blood and infusion fluid warmers designed to reduce complications associated with the infusion of blood or other liquids . They warm the fluid by means of an aluminum heat exchanger which is adjacent to an I.V. extension set through which the liquid to be heated flows. The electrically powered heat exchanger has a spiral groove through which the I.V. extension set is wrapped. There is no direct contact between the heat exchanger and infusate, the infusate only contacts the I.V. extension set.

The BW685 and BW685S operate on 120 VAC and are controlled by an on-off switch on the plastic face of the instrument. Above the on-off switch is an LED indicator which indicates the temperature setting as well as the measured temperature. The set temperature is selectable in increments of 0.5° C between 37 and 41°C. The default temperature is 38.5° C. The infusate is warmed to approximately the set temperature as it travels a path around the constantly monitored and regulated heat exchanger. The temperature is measured at the end of the extension set, where it leaves the spiral groove.

The BW685 / BW685 S weigh 1.9 and 2.0 kg respectively and are equipped with a dual knob clamp at the back of the devices for attachment to an I.V. pole; the devices may also be clamped to a bedrail.

The BW685 and BW685S are identical except that the BW685 S has provision and additional circuitry for connection to an additional heating element that can be placed

510(k) Summary
Page 2 of 7
18-Apr-2012

nearer the patient. The additional heating element is called the TubeFlow and fits over the I.V. line to the patient. The TubeFlow is electrically powered from the BW685S and contains a display indicative of the heating status (green for heating) or over-temperature (red). The TubeFlow does not contain software.

Indications for Use:
The BW685/BW685 S blood / fluid warming system is intended to deliver warm blood, blood products, and liquids to adult and pediatric patients.

Patient Population: Adult and pediatric

Environment of Use: Hospital

Contraindications: None

Table of Comparison and Differences vs. Predicates

We present a comparison of the proposed device and the predicate in the following table and then discuss the table and any differences.

510(k) Summary
Page 3 of 7
18-Apr-2012

Comparison to Predicate

Attribute	Biegler GmbH BW385L K954769	Biegler GmbH BW685 and BW685 S	Equivalency to at least one or both devices
Indications for Use	The Biegler BW385L Blood & Infusion Warmer was specifically designed to reduce the complications associated with the moderate rate infusion of cold blood and liquids.	The BW685/S blood / fluid warming system is intended to deliver warm blood, blood products, and liquids to adult and pediatric patients.	Similar
Environments of use	Hospital	Hospital	Identical
Principle of operation	Continuous flow electrically powered warmer	Continuous flow electrically powered warmer	Identical
Warm up time	45-55 seconds	45-55 seconds	Identical
Ingress Protection	IPX1	IPX4	Better liquid ingress protection in BW685 and BW685S
Degree of protection against electric shock	Type B	Type B	Identical
Dimensions	140 x 190 x 240mm	228 x 278 x 132mm	
Prescriptive	Yes	Yes	Identical
Patient population	adult and pediatric	adult and pediatric	Identical
Single patient reusable	Yes for accessories	Yes for accessories	Identical
Accessories	3 extension sets	3 extension sets Tube Flow	The three extension sets used with the BW685/S are identical to those in K954769 Tube Flow is an option for the BW685S, details below

510(k) Summary
Page 4 of 7
18-Apr-2012

Attribute	Biegler GmbH BW385L K954769	Biegler GmbH BW685 and BW685 S	Equivalency to at least one or both devices
Heating Mechanism	Heating cylinder around which is wrapped an extension set	heating cylinder around which is wrapped an extension set, additional heating with TubeFlow	Identical except for TubeFlow. TubeFlow provides additional heating near patient to compensate for any thermal losses between 685S and patient.
Fluid Contact materials	Extension sets PVC, ABS	Extension sets PVC, ABS	Identical The extension sets are identical in every respect
Temperature Control	3 sensors: 1 monitored by software, two hardware	3 sensors: 1 monitored by software, two hardware	Identical
Alarm	Audio/Visual	Audio/ Visual	Identical
Product Code	LGZ	LGZ	Identical
Alarm Conditions	Audible and Visual Low temperature (<36.5C) High Temperature (>42.0C)	Audible and Visual Low temperature (<36.5C) High Temperature (>42.0C)	Identical
Operation	110/220 VAC with AC power	110/220 VAC with AC power	Identical
Electronics	Microprocessor Control	Microprocessor Control	Identical
Infusion Temperature	Fixed at 38.5°C	User selectable between 37 to 41°C at increments of 0.5° Default 38.5°C Tube Flow: Fixed 39.0°C	Identical, except for TubeFlow

510(k) Summary
Page 5 of 7
18-Apr-2012

Attribute	Biegler GmbH BW385L K954769	Biegler GmbH BW685 and BW685 S	Equivalency to at least one or both devices
Tube Flow	Not present	Present on BW685S	The additional heating element is called the TubeFlow and clamps over the I.V. line to the patient. The TubeFlow is electrically powered from the BW685S and contains a display indicative of the heating status (green for heating) or over temperature (yellow).
Tube Flow Materials	NA	Housing: Same material as BW685 S housing: Sabic Cycoloy Resin C2800 There are no materials of the TubeFlow which contact the patient or infusate.	
Tube Flow Control	NA	The TubeFlow does not contain software. The addition in the BW685S is a power supply and sensing and control circuitry for controlling temperature in the TubeFlow.	
Tube Flow Set Temperature	NA	39.0°C	
Tube Flow Temperature Control	NA	The TubeFlow contains an independent temperature sensor. It also contains an independent temperature sensor in the silicone profile to detect over-temperature.	

510(k) Summary
Page 6 of 7
18-Apr-2012

Discussion:
There are no significant differences which would affect safety and efficacy for patient safety.

Substantial Equivalence
The warming methodology of the BW685 and BW685 S are identical to the predicate. The fluid contact extension sets used with the BW685 and BW685 S are identical to the predicate.

The fundamental scientific technology of the BW685 and BW685 S is identical to the predicate.

The differences that exist between the devices are insignificant in the terms of safety or effectiveness.

Indications – Equivalent to the predicate

Technology – The technology is identical

Operating specifications – Equivalent–

Materials – The fluid contact materials are identical.
The only patient contact is the fluid / blood via the extension sets provided by Biegler for exclusive use with the proposed blood / fluid warmer. The extension sets are identical to those used in the predicate.

Environment of Use – Identical

Patient Population – Identical

Differences:
There are no significant differences between the proposed device and the predicate device.

510(k) Summary
Page 7 of 7
18-Apr-2012

Comparative Performance and Specifications
We have performed the following testing:

- Leakage testing
- Heater testing at various flow rates
- Fault testing
- Testing to the requirements of ASTM F2172-02 Standard Specification for Blood/ Intravenous Fluid/Irrigation Fluid Warmers

WE have also performed testing to ensure that the proposed device met its specifications. As well we have done a comparison of specifications in the above tables and found the proposed models to be equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Biegler GmbH
C/O Mr. Paul Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134

JUL 12 2012

Re: K121198
Trade/Device Name: BW685 and BW685S
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LGZ
Dated: June 18, 2012
Received: June 20, 2012

Dear Mr. Dryden:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K121198 (To be assigned)

Device Name: **BW685 and BW685S**

Indications for Use:

The BW685/BW685 S blood / fluid warming system is intended to deliver warm blood, blood products, and liquids to adult and pediatric patients.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (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)

7/11/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121198