

OCT 06 2008

## 510(k) Summary of Safety & Effectiveness

This 510(k) Summary of Safety & Effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92. The device is a Class II device called the Ranger<sup>®</sup> Rapid Flow<sup>™</sup> blood/fluid warming system.

**Submitter**

Arizant Healthcare Inc.  
10393 West 70<sup>th</sup> Street, Eden Prairie, MN 55344

**Date Prepared**

July 31, 2008

**Trade/Proprietary Name**

Ranger<sup>®</sup> Rapid Flow<sup>™</sup> blood/fluid warming system

**Common/Usual Name**

Blood/Fluid Warmer with Pressure Infusor

**Classification Name**

Warmer, Thermal, Infusion Fluid

**Predicate Devices**

Arizant Healthcare Inc. Bair Hugger blood/fluid warmer (K973741)  
Level 1<sup>®</sup> H-1028 Fluid Warming System (BK020043)

**Intended Use**

The Ranger Rapid Flow blood/fluid warming system is intended to deliver warm blood, blood products, and liquids to adult and pediatric patients.

## **Description of Device**

The Ranger Rapid Flow blood/fluid warming system is a stand-alone system that warms fluid, detects fluid level within the bubble trap, controls a patient valve, and delivers high volumes of fluid under pressure. The warming system consists of warming plates, fluid detection, valve control, pressure infusors and a fluid warming disposable set.

### ***Ranger Rapid Flow blood/fluid warming unit***

The warming unit consists of the electronic control circuitry and aluminum plates contacted by heating elements, also known as dry-heat. With a setpoint of 42°C that is PID controlled, the displayed temperature is an average of the fluid and plate temperature.

The air detection has two sensors that detect the fluid level (absence of air) and controls a patient valve. If the fluid level is not adequate, the patient valve closes and stops flow to the patient. When the fluid level is adequate the patient valve opens, allowing the flow of fluid to the patient. This functionality is also tied to the operation of the pressure infusors. If the patient valve closes, the pressure is exhausted from the pressure infusors. Only if the fluid level is adequate and the valve is open can the pressure infusors be pressurized. The pressure infusor interface provides feedback to the user.

The pressure infusors accept solution bags ranging from 250cc to 1000cc. Each side of the pressure infusor is controlled independently. The pressure infusors are set to 300 mmHg and provide fluid under pressure to achieve a higher flow.

The system continuously monitors temperature and detects air in the fluid path to ensure safe operation and alarms at all unsafe conditions. The main panel on the front of the unit displays the temperature and status of the warming unit.

### ***Ranger Rapid Flow disposable set***

The disposable set is an integral component to the Ranger Rapid Flow blood/fluid warming system. The set has spike/filter drip chambers, heat exchanger, bubble trap, patient line with injection ports, tubing, luer locks, and other standard administration set components. The spike/drip chambers can be easily replaced during a procedure. There is an option for dual or triple spike disposable sets. The heat exchanger makes contact with the heating plates to warm the fluid. The bubble trap captures and vents air from the system. Sensors monitor the fluid level within the bubble trap and control a valve on the disposable to stop or allow flow to the patient.

## Comparison of the Technological Characteristics of the New Device and Predicate Devices

The Ranger<sup>®</sup> Rapid Flow blood/fluid warming system is substantially equivalent to the Bair Hugger blood/fluid warmer (K973741) and Level 1<sup>®</sup> H-1028 Fluid Warming System (BK020043).

Comparison of Technological Features

Features	Ranger Rapid Flow Blood/Fluid Warming System	Bair Hugger Blood/Fluid Warmer	Level 1 H-1028 Fluid Warming System
Flow rates	KVO-1200 mL/min	KVO-500 mL/min	KVO-1400 mL/min
Method of operation	Aluminum plate heated by electrical resistance; disposable cassette contacts plates	Aluminum plate heated by electrical resistance; disposable cassette contacts plates	Fluids are warmed through the use of a sealed heat exchanger through which a recirculating solution flows.
Electronics	PID-controlled	PID-controlled	Uses water bath technology controlled electronics
Temperature Control	Electronically Controlled	Electronically Controlled	Electronically Controlled
Alarms	Audible and visual under and over temperature; alarms activate when temperature is at 25°C, at 45.5°C, and at 46°C.	Audible and visual under and over temperature; alarms activate when temperature is at 33°C, at 43°C, and at 46°C.	Audible and visual over temperature alarms activate when temperature is at 43.9°C.
Tubing	<ul style="list-style-type: none"> <li>▪ 144" long, 0.185" min ID, 0.273 max OD.</li> <li>▪ Patient Line: 84" long, 0.185" min ID, 0.273 max OD.</li> </ul>	<ul style="list-style-type: none"> <li>▪ 144" long, 0.185" min ID, 0.273 max OD.</li> <li>▪ Patient Line: 84" long, 0.185" min ID, 0.273 max OD.</li> </ul>	<ul style="list-style-type: none"> <li>▪ 68" long, 0.185" max ID, 0.273" min ID.</li> <li>▪ Patient Line: 87" long, 0.185" min ID, 0.273 max OD.</li> </ul>
Sterilization method	100% Ethylene Oxide, reference Isomedix Soft Cycle.	100% Ethylene Oxide, reference Isomedix Soft Cycle.	100% Ethylene Oxide, reference Isomedix Soft Cycle.
Disposable packaging	The disposable set will be manufactured and assemble in a filtered air environment. Prior to exiting the filtered air environment, each disposable set will be placed in a box and then sealed within a pouch. The pouch is made of polyethylene and tyvek header which have been proven to resist tearing or puncturing.	The disposable set is manufactured and assemble in a filtered air environment. Prior to exiting the filtered air environment, each disposable set will be placed in a box or sealed within a pouch. The pouch is made of polyethylene and tyvek header which have been proven to resist tearing or puncturing.	The disposable set is placed within a box.

**Discussion of Nonclinical Studies and Clinical Tests**

Clinical tests were not necessary regarding the use of the Ranger Rapid Flow blood/fluid warming system.

**Conclusion**

The Ranger Rapid Flow blood/fluid warming system has similar technological characteristics, components, and materials, and the same intended use as devices currently on the market. Therefore, because of the similarities to the predicate devices, Arizant Healthcare believes this new device does not raise any new safety or effectiveness issues.

**Contact**

David Westlin

Chief Compliance Officer and Senior Director of Regulatory Affairs, Arizant Healthcare Inc.



Food and Drug Administration  
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Rockville MD 20850

OCT 06 2008

Mr. David Westlin  
Chief Compliance Officer  
Senior Director of Regulatory Affairs  
Arizant Healthcare Incorporated  
10393 West 70<sup>th</sup> Street  
Eden Prairie, Minnesota 55344

Re: K082217  
Trade/Device Name: Ranger Rapid Flow Blood/Fluid Warming System  
Regulation Number: Unclassified  
Regulation Name: None  
Regulatory Class: Unclassified  
Product Code: LGZ  
Dated: October 1, 2008  
Received: October 2, 2008

Dear Mr. Westlin:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

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

510(k) Number (if known): \_\_\_\_\_

Device Name:

Ranger Rapid Flow Blood/Fluid Warming System

Indications For Use:

The Ranger Rapid Flow blood/fluid warming system is intended to deliver warm blood, blood products, and liquids to adult and pediatric patients.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

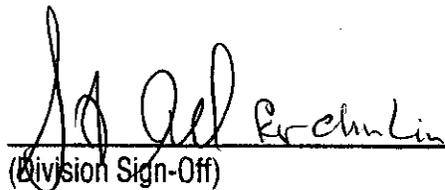
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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510(k) Number:   K082217