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Baxter

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510(k) Summary

Submitter

Baxter Healthcare Corporation
I. V. Systems Division
Route 120 and Wilson Road
Round Lake, IL 60073

Contact

Jody Ann Gould, Ph.D.
Phone: (708) 270 - 4014
Fax: (708) 270 - 4668

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Trade/Proprietary Name

ThermaCyl™ Blood/Fluid Warmer

Common/Usual Name

Blood/fluid warmer

Classification Name

Nonelectromagnetic blood or plasma warming device

Predicate Devices

Pharmaseal DW 1000 Blood/Fluid Warmer
Alton Dean Blood Warmer

Description of Device

The ThermaCyl™ blood/fluid warmer consists of a warming device (hardware) and a container (disposable) designed for use with the hardware. The device is capable of warming blood products or intravenous fluids, flowing at rates of up to 500 mL/minute, to temperatures of as high as and including 42°C (in accordance with American Association of Blood Banks (AABB) Standards for Blood Banks and Transfusion Services).

Two types of disposables are available. A standard blood/fluid warming cuff for use with standard administration sets and a high flow blood/fluid warming cuff for use with mass infusion sets. The disposables are composed of the same materials used in the current Pharmaseal blood warming device disposable. They are designed to surround the aluminum cylinder of the warming device. The disposable is in direct contact with the



cylinder. The cylinder is heated by means of electrical resistance. Blood products or intravenous fluids are heated as they flow through the bag. The temperature of the cylinder is accurately controlled by the device's electronics. The electrical requirements are designed in accordance with UL 2601. The device also meets the requirements of CSA 601. No software is used.

Statement of Intended Use

The ThermoCyl™ blood/fluid warmer is indicated for the warming of blood products and intravenous solutions prior to administration. It is intended to be used by healthcare professionals in clinical environments.

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

The ThermoCyl™ blood/fluid warmer is substantially equivalent to the Pharmaseal blood/fluid warmer (found substantially equivalent under K770232) and the Alton Dean blood/fluid warmer (found substantially equivalent under BK910033). A comparison of technological features follows:

FEATURE	ALTON DEAN BLOOD WARMER	BAXTER THERMACYL™ BLOOD/FLUID WARMER	PHARMASEAL BLOOD/FLUID WARMER (DW-1000D)
Maximum Flow Rate	> 500 mL/minute	500 mL/minute	200 mL/minute
Heating Method	Metal plate heated by electrical resistance; disposable bag in direct contact with plate	Metal cylinder heated by electrical resistance; disposable bag in direct contact with cylinder	Metal cylinder heated by electrical resistance; disposable bag in direct contact with cylinder
Temperature Control	Adjustable set point; internal sensors	Thermistors (2 inlet; 2 outlet)	Three control thermostats
Alarm Description	Audible and visual alarms	Audible and visual alarms	Audible and visual alarms
Alarm Conditions	Temperature exceeds adjustable set point (up to 39.5°C)	Thermistor temperature exceeds 42°C; Thermistor pair's temperatures differ by ≥ 5°C	Temperature reaches over-temperature thermostat range 41.7 - 44.7°C
Electronics	Microprocessor control	UL 2601 and CSA 601	UL 551

Discussion of NonClinical Studies

A study was conducted to evaluate the hemolytic effects of the redesigned blood/fluid warmer. Whole blood, packed red blood cells and Adsol preserved red blood cells near outdate were tested. Percent hemolysis was evaluated before and after flow through the blood warming device at less than 100 mL/minute and at the highest flow rate possible for each type of blood. There was minimal or no hemolysis for all bloods and variables tested.