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## 5 510(k) Summary

**Date:** 2011-10-24

**Submitter:** Barkey GmbH & Co. KG

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**Common Product Name:** **Blood and Plasma Warming Device**

**Trade Name:** **plasmatherm**

**Regulation Medical Specialty (Panel):** Hematology  
[21 CFR 864.9205]

**Product Code:** KZL

**Device Class:** 2

**Identification of legally marketed predicate devices to which substantial equivalence is claimed:**

CytoTherm CT-D4  
510(k) Number: BK060027  
[21 CFR 864.9205]  
CytoTherm LP  
110 Sewell Avenue  
Trenton, NJ 08610  
US

Sahara Blood and Plasma Warming Device  
510(k) Number: BK010045  
[21 CFR 864.9205]  
Sarstedt, Inc.  
P.O. Box 468  
Newton, NC 28658-0468  
US

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**Brief Description:**

The Barkey plasmatherm is configured as an electronically regulated dry heating device with an enclosed heating chamber. The blood components of e.g. fresh frozen plasma (FFP), plasma frozen within 24 hours after phlebotomy (PF24), cryoprecipitated AHF, whole blood, red blood cells (RBC), and crystalloid infusion solutions are placed between soft heating cushions made from a flexible synthetic material. Distilled or demineralised water flows through the heating cushions which thaws or warms the materials placed in the device.

All heating is controlled by heating programs. To heat a particular preparation, the user selects the appropriate program on the operating panel using the display and buttons.

**Indications for Use:**

The Barkey plasmatherm is a thawing and warming device intended for the following applications:

- warming of Whole Blood
- warming of Red Blood Cells
- thawing of Fresh Frozen Plasma (FFP)
- thawing of Plasma Frozen within 24 Hours after Phlebotomy (PF24)
- thawing of Cryoprecipitated AHF
- warming of crystalloid infusion solutions

prior to transfusion.

**Summary of Nonclinical Tests and Results:**

The plasmatherm complies with the safety standards below and is therefore safe and effective for the intended use. Verification of compliance with the following mandatory and voluntary standards has been made:

EN 60601-1:1990 + A1:1993 + A2:1995  
UL 60601-1:2003 R6.03  
EN 60601-1-2:2007  
AABB Technical Manual

All performance testing has been performed with human derived blood products; means:

- Whole blood @ 500 ml/bag
- Red Blood Cells @ 300 ml/bag
- Fresh Frozen Plasma @ 300 ml/bag
- Plasma Frozen within 24 hrs after Phlebotomy @ 300 ml/bag
- Cryoprecipitated AHF @ 40 ml/bag

Due to the objectives of the testing this is distinguished as to be adequate.

The samples of Fresh Frozen Plasma, Plasma Frozen within 24 hrs after Phlebotomy and Cryoprecipitated AHF were frozen flat and free of crinkles at -30°C for at least 24 hrs minimum. The thawing time for Fresh Frozen Plasma and Plasma Frozen within 24hrs after Phlebotomy to be ice free was recorded, ranging up to approx. 13 minutes. The thawing time for Cryoprecipitated AHF to be ice free was recorded, ranging up to approx. 2 minutes.

The samples of Whole Blood and Red Blood Cells were stored flat and free of crinkles at + 2°C for at least 24 hrs minimum. The warming time for Whole Blood to reach 36°C was recorded, ranging up to approx. 21 minutes. The warming time for Red Blood Cells to reach 36°C was recorded, ranging up to approx. to 13 minutes.

The predicate devices have not been removed from the market at the initiative of the Commissioner of Food and Drugs or has not been determined to be misbranded or adulterated by a judicial order.

**Conclusion:**

The plasmatherm is substantially equivalent to the predicate devices. The systems have the same intended use, and are capable to:

- warm Whole Blood
- warm Red Blood Cells
- thaw Fresh Frozen Plasma (FFP)
- thaw Plasma Frozen within 24 Hours after Phlebotomy (PF24)
- thaw Cryoprecipitated AHF
- warm crystalloid infusion solutions

The in house Bench-Testing of the plasmatherm in comparison to the predicate devices shows that the proposed plasmatherm thaws FFP, PF 24 and Cryoprecipitated AHF at the same rate and at the same temperature as the previously approved predicate devices.

The plasmatherm's temperature setting and thawing times are in compliance to the requirements stated in AABB formerly known as the American Association of Blood Banks Technical Manual and 21CFR606.122(m)(2) and 21CFR606.122(n)(4).

The in house Bench-Testing of the plasmatherm in comparison to the predicate devices shows that the proposed plasmatherm warms Whole Blood and Red Blood Cells at the same rate and at the same temperature as the previously approved predicate devices.

The in house Bench-Testing of the plasmatherm in comparison to the predicate devices shows that the proposed plasmatherm

thaws at the same rate and at the same temperature as the previously approved predicate devices.

This shows that there are no new questions of safety and effectiveness for the plasmatherm as compared to the predicate devices.