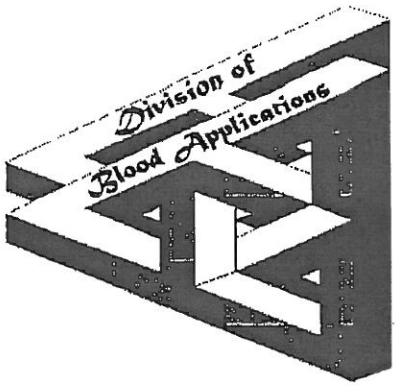

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
FOOD AND DRUG ADMINISTRATION
OFFICE OF BLOOD RESEARCH AND REVIEW
DIVISION OF BLOOD APPLICATIONS

Woodmont Office Complex, 400N
1401 Rockville Pike
1401 Rockville, Maryland 20852-1448

FACSIMILE TRANSMISSION RECORD

TOTAL NUMBER OF PAGES: 4 (Including Cover Page)

FAX TO: Mr. Thomas Barkey, Barkey GmbH & Co. KG

Facsimile Telephone No. 49 5202 98 01 77 Voice Telephone No. _____

FROM: Kim Hubbard

Facsimile Telephone No. 301-827-2857 Voice Telephone No. _____

DATE: Nov 21, 2011 **TIME:** _____

NOTICE: *CALL* _____ *FOR IMMEDIATE PICK UP.*

Letter for BK100063

NOTE: If you do not receive a legible document, or do not receive all of the pages, please telephone us immediately at the voice number above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

November 17, 2011

Barkey GmbH & Co. KG
Attention: Mr. Thomas Barkey
Gewerbestrasse 8
D-33818 Leopoldshoehe
Germany

Re:	BK100063
Trade/Device Name:	plasmatherm
Regulation Number:	21 CFR 864.9205
Regulation Name:	Blood and plasma warming device
Regulatory Class:	Class II
Product Code:	KZL
Dated:	November 17, 2011
Received:	November 17, 2011

Dear Mr. Barkey:

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 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 contact our Advertising and Promotional Labeling Staff (HFM-602) at (301) 827-3028. 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,

Richard J. Davey, M.D.

Richard J. Davey, M.D.
Director
Division of Blood Applications
Office of Blood Research and Review
Center for Biologics
Evaluation and Research

Enclosure

Indications for Use

510(k) Number: BK100063/0

Device Name: plasmatherm

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.

WARNING: The plasmatherm device cannot be used to warm previously thawed Cryoprecipitated AHF, Platelets and Granulocytes.

CAUTION: It is intended to be used only by appropriately trained and qualified healthcare professionals and servicing staff in clinical environments.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CBER, Office of Blood Research and Review

Randy J. Davey, MD

Division Sign-Off
Office of Blood Research and Review