510(K) SUMMARY
August 15, 2008

DEC 19 2008

SUBMITTER INFORMATION: (Registration#: 9617473)

Stihler Electronic GmbH
Julius-Holder-Strasse 36
D-70597 Stuttgart (Degerloch)
Germany

APPLICANT/FDA AGENT/CORRESPONDING OFFICIAL INFORMATION:

North American Technical Services (NATS) Corp
30 Northport Rd
Sound Beach, NY 11789
Tel: 631-744-0059 Fax: 631-744-0192 Email: natscorp.@aol.com
Contact: Stephen T. Mlcoch

DEVICE NAME:

Name: Blood Warmer
Proprietary Model: PRISMAFLO II
Classification: 2
Product Code: KOC
Regulation: Gastroenterology – Urology Devices (21CFR876.5820)

PREDICATE DEVICES:

Stihler Electronic GmbH, Blood Warmer Model PRISMAFLO – K020103
Barkey GmbH + Co. KG, Blood Warmer Model Prismacomfort – K071909

DESCRIPTION:

The PRISMAFLO II is a modified version of the PRISMAFLO covered by K020103. The PRISMAFLO uses water in the heat transfer process. PRISMAFLO II is the same as PRISMAFLO except it is water free.

The PRISMAFLO II dialysis fluid and blood warmer is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Barkey Prismacomfort 510(K) Number K071909. The PRISMAFLO II blood warmer is used to warm the return blood flow line in order to replace heat lost to the atmosphere and effluent flow during a Prismaflex or PRISMA treatment. The PRISMAFLO II blood warmer consists of one control unit and one sleeve warmer. The control unit (Stihler PRISMAFLO II) controls the sleeve warmer and displays alarm and status messages.

The PRISMAFLO II blood warmer warms the returning blood flow line by means of a silicon tube heat exchanger which covers the blood return flow line of the Gambro Prismaflex or Prisma system completely. The heat is transferred by the contact of the resistance heating system to the inserted blood return line. The complete enclosure of the returning blood flow line to be warmed ensures that there are no temperature losses to the surroundings. The warmth produced by the sleeve warmer is therefore transferred to the return blood flow at maximum efficiency.

The sleeve warmer is powered with 22 VDC which is derived from 115 VAC (or where required 230 VAC), 50/60 Hz power supply and is controlled by an on-off switch on the front panel of the control unit Stihler PRISMAFLO II. Above the on-off switch is a display temperature monitor showing actual and set temperature. The temperature of the sleeve warmer and other performance characteristics of the sleeve warmer are controlled electronically, visual and audible alarms as well as cut-offs are hardware realized. Like the blood warmer Barkey Prismacomfort, the sleeve warmer PRISMAFLO II is constructed as a slotted enclosed silicon tube, which can completely enclose inserted blood return flow lines of up to 7.00 mm diameter. The PRISMAFLO II weighs approx 3.9 kg and is equipped with a holder at the rear side of the control unit, which allows mounting on hemodialysis system Gambro Prismaflex and Prisma system. Both products, the PRISMAFLO II and the Barkey Prismacomfort use sleeve warmers made of silicon. The flexibility of this material ensures a nearly complete enclosure of the blood return flow line on Gambro Prismaflex and Prisma system.

Only the water free operation of the PRISMAFLO II differs to the PRISMAFLO.

INTENDED USE:

The PRISMAFLO II is for warming dialysis fluid and returning blood flow.

Federal law restricts this device to sale by or on the order of a physician. It is intended to be used only by appropriately trained and qualified healthcare professionals and servicing staff in clinical environments.

SUMMARY OF NONCLINICAL TESTS AND DESIGN CONTROL ACTIVITIES:

The PRISMAFLO II blood warmer complies with the safety standards below and is therefore safe for the intended use. The device has been thoroughly tested through validation and verification of specifications. Verification of compliance with the following mandatory and voluntary standards has been made:

- DIN EN 60601-1
- DIN EN60601-1-2
- UL 2601-1/10.97
- CAN/CSA-C22.2 No. 601.1-M90
- ASTM F 2172-02 (USA Standard for Blood and Fluid Warmers)

In order to verify effective performance of the Stihler PRISMAFLO II blood warmer in support of substantial equivalence, the following tests were carried out successfully:

- Verify the ability of the system to prevent cooling down of blood return lines on Gambro Prismaflex CRRT system.
- Verify the ability of the system to protect the patient and to detect and alarm at unsafe operating conditions.

This control activity shows that there are no new questions of safety and effectiveness for the PRISMAFLO II blood warmer as compared to the predicate devices.

CONCLUSION:

The PRISMAFLO II blood warmer is substantially equivalent to the Barkey Prismacomfort. Both systems have the same intended use and are capable of heating blood return flow line on Gambro Prismaflex system. Both systems are the same according to the specifications of the device. Both use a water free heat reference to initiate the heat transfer process.

The PRISMAFLO II is the same as the PRISMAFLO made by Stihler except for the water free operation. The water free modification is safe and effective per the controlled design process and equivalence to the predicate device.

(stihler /8047fm)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 2008

Stihler Electronic GmbH
c/o Mr. Stephen T. Mlcoch
FDA Agent & Corresponding Official
North American Technical Services Corp.
30 Northport Road
SOUND BEACH NY 11789-1734

Re: K082758
Trade/Device Name: PRISMAFLO II
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KOC
Dated: December 8, 2008
Received: December 10, 2008

Dear Mr. Mlcoch:

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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

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 Biometrics' (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,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# INDICATIONS FOR USE

Special 510(K) Number: K082758

Modified Device Name: PRISMAFLO II

Indications for Use: For warming dialysis fluids and returning blood flow.

Prescription Use X
(Per 21 CFR 801.109)

(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 Reproductive, Abdominal and
Radiological Devices
510(k) Number K082758