510(K) SUMMARY
August 18, 2008

DEC 18 2008

SUBMITTER INFORMATION:

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 and Infusion Warmer
Proprietary Model: ASTOFLO PLUS
Classification: 2
Product Code: BSB
Regulation: (864.9205) Warmer, Thermal, Infusion Fluid Warmer, Blood, Non-Electromagnetic

PREDICATE DEVICES:

Stihler Electronic GmbH, Blood Warmer Model ASTOFLO – K020060
Barkey GmbH + Co. KG, Blood Warmer Model Prismacomfort – K071909

DESCRIPTION:

The ASTOFLO PLUS is a modified version of the ASTOFLO covered by K020060. The ASTOFLO uses the closed water circuit where the temperature of the closed water circuit is controlled by sensors. ASTOFLO PLUS uses dry heat warming and the control the sleeve temperature with integrated sensors.

The ASTOFLO PLUS blood warmer is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Stihler ASTOFLO 510(K) Number 020060 and Barkey Prismacomfort 510(K) Number K071909. The ASTOFLO PLUS blood warmer is used to warm the transfusions, infusions, fluids and also return blood flow in the medical field. The ASTOFLO PLUS warmer consists of one control unit and one sleeve warmer. The control unit (ASTOFLO PLUS) controls the sleeve warmer made by Stihler and displays alarm and status messages.

The ASTOFLO PLUS warmer warms blood, infusions, fluids and return blood flow by means of a silicon tube heat exchanger, which covers the fluid lines used in the medical field nearly complete. The heat is transferred by the contact of the resistance heating system to the inserted disposable lines need in the medical field. The nearly complete enclosure of the disposable lines used in the medical field to be warmed ensures that there is good warmth conduction to the fluids and there are no temperature losses to the surroundings. The warmth produced by the sleeve warmer is therefore transferred to the disposable lines used in the medical field and may be used with any therapy choices, when heat loss may cause undesirable cooling of the patient.

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 ASTOFLO PLUS. Above the on-off switch is a display temperature monitor. The temperature of the sleeve warmer visual and audible alarms and other performance characteristic of the sleeve warmer are controlled electronically. Like the blood warmer Stihler ASTOFLO and the Barkey Prismacomfort, the sleeve warmer Stihler ASTOFLO PLUS 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 ASTOFLO Plus weighs approx 3.0 kg and is equipped with a holder at the rear side of the control unit, which allows mounting on i.v. poles and medical rails. All three products, the Stihler ASTOFLO PLUS, Barkey Prismacomfort and the Stihler ASTOFLO use sleeve warmers made of silicon. The flexibility of this material ensures a nearly complete enclosure of the disposable lines used in the medical field.

INTENDED USE:

The ASTOFLO PLUS warmer is used for 1. Warming transfusions, infusions. 2. Warming blood transfusions and return 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 ASTOFLO PLUS blood, infusions, fluid and return blood flow warmer complies with the safety standards below and is therefore safe for the intended use. The device has been tested through validation and verification of specifications. Verification of compliance with the following mandatory and voluntary standards has been made:

- DIN EN60601-1
- DIN EN60601-1-2 (All EMC and Immunity references)
- UL 2601-1/10.97
- CAN/CSA-C22.2 No. 601.1-M90
- ASTM F 2172-02 (USA Standard for Blood and Fluid Warmers)
- IEC60601-2-16:1998 (reference Standard for dialysate temperature)

In order to verify effective performance of the Stihler ASTOLFO PLUS blood, infusions and return blood flow warmer in support of substantial equivalence, the following tests were carried out successfully:

- Verify the ability of the system to warming fluids and to prevent cooling down of blood, infusions and return blood flows used in all therapy choices of the medical field.
- 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 ASTOFLO PLUS blood, infusions, fluid and return blood flow warmer as compared to both of the predicate devices including the modified device.

CONCLUSION:

The ASTOFLO PLUS blood, infusions, fluid and return blood flow warmer is substantially equivalent to the Stihler ASTOFLO. ASTOFLO PLUS and ASTOFLO have the same intended use and are capable of heating blood, infusions, fluids and return flow line in the medical field. Both systems as intended according to the specifications of the device.

The ASTOFLO is the same as the ASTOFLO PLUS made by Stihler except the ASTOFLO PLUS consists of one control unit and one applied part (the sleeve warmer), the ASTOFLO is one complete system which means that the warming device is fix connected to the supply part (the control unit). The ASTOFLO PLUS uses dry heat and ASTOFLO uses the closed water circuit.

The ASTOFLO PLUS is substantially equivalent to Barkey Prismacomfort. Note equivalence items:

- have same fundamental scientific technology and use the same operating principle,
- heating sleeves are constructed of identical materials,
- both the ASTOFLO PLUS and the Prismacomfort give efficient heat to keep blood return line warm,
- both the ASTOFLO PLUS and the Prismacomfort use the same structure. Both consist of one control unit and one applied port (the sleeve warmer),
- both the ASTOFLO PLUS and the Prismacomfort use the same principle of dry heat warming and control the sleeve temperature with integrated sensors inside the sleeve.

(stihler /8046fm)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 2008

Stihler Electronic GmbH
C/O Mr. Stephen T. Mlcoch
North American Technical Services Corporation
30 Northport Road
Sound Beach, New York 11789

Re: K082765
Trade/Device Name: ASTOFLO PLUS
Regulation Number: None
Regulation Name: Blood and Infusion Warmer
Regulatory Class: Unclassified
Product Code: LGZ
Dated: August 18, 2008
Received: September 22, 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 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 S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082765

INDICATIONS FOR USE

Modified Device Name: ASTOFLO PLUS

Indications for Use:

1. Warming transfusions, infusions, fluids.
2. Warming blood transfusions and return blood flow.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082765