September 4, 2020

Stihler Electronic GmbH
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K202197
Trade/Device Name: Astopad Patient Warming System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: Class II
Product Code: DWJ
Dated: August 4, 2020
Received: August 5, 2020

Dear Dave Yungvirt:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Fernando Aguel
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202197

Device Name
ASTOPAD Patient Warming System

Indications for Use *(Describe)*

The ASTOPAD® Patient Warming System is intended to prevent or treat hypothermia and to provide warmth to patients. The ASTOPAD Patient Warming System is indicated for use in all areas of healthcare facilities for preventing or treating hypothermia or maintaining normothermia. The warming blankets can be used over or under the patient (pediatric and adult) by appropriately trained healthcare professionals.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary K202197

I. SUBMITTER

Stihler Electronic GmbH
Julius-Hoelder-Strasse 36
70597 Stuttgart
Germany

Phone: +49-711-720670
Fax: +49-711-7206757

Contact person: Christina Miracle
Gentherm Medical, LLC
Director of Quality Assurance & Regulatory Affairs
phone: 513.326.5295
mail: christina.miracle@gentherm.com

Date of Preparation: 4 Sep 2020

Manufacturer: Stihler Electronic GmbH
Julius-Hoelder-Strasse 36
70597 Stuttgart
Germany

Establishment Registration Number: 9617473

II. DEVICE

Trade name: ASTOPAD® Patient Warming System
Model numbers: DUO310-NA, COV070-NA, COV105-NA, COV150-NA, COV155-NA, COV180-NA
Common name: Thermal Regulating System
Classification name: System, Thermal Regulation (21 CFR Part 870.5900, Product Code DWJ)
Class: Class II

III. PREDICATE DEVICE

HotDog Patient Warming System, K112488
This predicate has not been subject to a design-related recall.[1]

IV. DEVICE DESCRIPTION

The ASTOPAD Patient Warming System is a thermal regulating system which includes a connection cable that attaches to reusable conductive warming blankets for patient warming in clinical environments. The system consists of a control unit (DUO310-NA) and one or optionally two applied parts (warming blankets/COVXXX-NA) with different sizes to fit different applications:

[1] Source: FDA Medical Device Recalls database, last update 02/14/2020

COV070-NA[2] warming blanket, 680x480 mm
COV105-NA warming blanket, 1050x500 mm
COV150-NA warming blanket, 1500x500 mm
COV155-NA Arm-chest-warming blanket, 1500x500 mm (with cut-outs)
COV180-NA warming blanket 1800x800 mm

The ASTOPAD control unit is equipped with a universal mounting clamp for attaching to standard medical equipment rails or an infusion stand, two outputs for connecting one or two applied parts, connection to mains by detachable power supply cord, connector for potential equalization, the electronic boards and the control panel for the user/operator.

The control unit has two outputs (connecting sockets) A and B for connecting ASTOPAD applied parts. The desired set temperature can be selected in the range of 32.0 °C - 39.0 °C in 0.5 °C increments for each connected applied part, independent of each other, on the control panel of the control unit. The control unit can also be used with only one of the outputs, A or B. The selected set temperature and the current temperature are displayed individually for each applied part in the control panel.

The control unit supplies the applied part(s) with electrical current (low voltage) and monitors and controls the temperature of the applied part(s). When error conditions occur, the control unit draws the operator's attention to the error condition by means of alarm signals (optical & acoustical). In the event of failure conditions (overheating, heater defect, sensor defect), the control unit reacts immediately by shutting off the power supply to the applied part.

Optionally the control unit can be fitted with a battery. When the battery is installed, it is possible to operate the device independently from the mains for approximately two hours.

The ASTOPAD control unit does not control or indicate the actual temperature of the patient, but rather only the actual temperature of the applied part.

Temperature regulation of the individual applied parts is performed with several integrated sensors.

Safety of ASTOPAD is provided by the following measures per output:

- Several temperature sensors for each applied part
- Double independent sensor monitoring
- Heater monitoring
- Time shut-off
- Visual and acoustic alarm signals
- Overheating and low-temperature alarm if the contact surface temperature deviates from the temperature controller setting

[2] "NA" Refers to North America, with English labeling.

V. INDICATIONS FOR USE

The ASTOPAD® Patient Warming System is intended to prevent or treat hypothermia and to provide warmth to patients. The ASTOPAD Patient Warming System is indicated for use in all areas of healthcare facilities for preventing or treating hypothermia or maintaining normothermia. The warming blankets can be used over or under the patient (pediatric and adult) by appropriately trained healthcare professionals.

Both the subject device and the predicate device have the same intended use: to prevent or treat hypothermia and to provide warmth to patients.

The Indications for Use of the subject device are similar as that of the predicate device; however, the differences in wording do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device. Both the subject and predicate devices have the same intended use for the prevention or treatment of hypothermia and maintenance of normothermia for pediatric and adult patients in all areas of healthcare facilities.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Subject (New) Device	Predicate Devices
Control Unit		

Applied Parts

Comparison

Heat transfer to the patient, using conductive heat, is the technological principle for both the subject and predicate devices. It is based on the use of applied parts which have thermal contact with the patient to provide heat.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Applied parts in the form of blankets are lightweight and flexible and both are made from coated plastics.
- Applied parts are powered by electrical energy (low voltage).
- Electrical energy is transformed to warmth by a heating element which opposes the current by an electrical resistance.
- Temperature of the applied parts is controlled by temperature sensors.
- The systems include a control unit and applied parts in different sizes.
- Control units and applied parts are connected together by a detachable cable.
- Control units include attachment device for IV-pole or medical rail, control and monitoring electronics, control panel for the user, outputs to connect applied parts simultaneously, and input for power supply cord.
- User can select set temperature of the applied parts within a limited range.
- Control panels show set temperature of the applied part.
- The control units inform the user about alarm conditions by means of optical and acoustic signals.
- Control units react with an alarm in the case of sensor defects
- Control units include a connector for potential equalization.
- Control units have a grip tray on the upper backside, with which the device can be transported with one hand.

The following technological differences exist between the subject and predicate devices:

- The subject device uses 8 temperature sensors for temperature control and monitoring, whereas the predicate device uses 2 temperature sensors for temperature control and monitoring.
- Each blanket of the subject device can be placed over or under the patient and can be used on either side, whereas the applied parts of the

predicate device are either over blankets or underbody mattresses that cannot be used interchangeably and can only be used on one side.
- The subject device is classified as "defibrillation-proof" according to the requirements of IEC 60601-1, whereas the predicate device is not.
- The subject device shows the user selected set temperature and the current temperature of the applied part simultaneously, whereas in operation mode the predicate device shows only the set temperature of the applied part.
- Based on the requirements of IEC 80601-2-35 the subject device has a set temperature range from 32°C to 39°C in 0.5°C increments. The predicate device has a selectable set temperature range from 37°C to 43°C in 1°C increments for blankets and 35°C to 39°C for mattresses.
- The subject device uses hardware for controlling and monitoring the temperature of the applied part, whereas the temperature control of the predicate device is managed by Microprocessor utilization.
- The subject device can optionally be fitted with a chargeable battery which makes it possible to operate the device independently from the mains for approximately two hours.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the ASTOPAD Patient Warming System was conducted as recommended by FDA's Guidance for Industry and FDA Staff, "Use of International ISO 10993-1, Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process".
The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

Electrical Safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the ASTOPAD Patient Warming System, consisting of the control unit and different applied parts. Testing shows the system complies with the applicable requirements of IEC 60601-1, IEC 60601-1-6, IEC 60601-1-8 and IEC 80601-2-35 standards for safety and IEC 60601-1-2 standard for EMC.

Documentation for claiming electromagnetic compatibility was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices".

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

The software for this device was considered as a "minor" level of concern, since a failure or a latent flaw in the software could not result in injury to the patient or operator.

Mechanical testing

Mechanical testing was conducted on the ASTOPAD Patient Warming System within the testing of the standards IEC 60601-1 and IEC 80601-2-35.

Testing shows the system complies with the applicable mechanical requirements of the standards.

Thermal testing

Thermal testing was conducted on the ASTOPAD Patient Warming System within the testing of the standards IEC 60601-1 and IEC 80601-2-35.

Testing shows the system complies with the applicable thermal requirements of the standards.

Human Factors Validation Testing

Human factors validation testing for the ASTOPAD Patient Warming System was conducted as recommended by FDA's Guidance for Industry and FDA Staff, "Applying Human Factors and Usability Engineering to Medical Devices".

The ASTOPAD system has been found to be safe and effective for the intended users, use and use environments.

Reprocessing Testing

The ASTOPAD Patient Warming System is classified as a reusable medical device which requires cleaning and disinfecting after each use. Cleaning and disinfecting validation were conducted as recommended by FDA's Guidance for Industry and FDA Staff, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling".

Required cleaning and disinfection validation testing were conducted on the control unit and on the applied part.

ASTOPAD Patient Warming System meets the applicable cleaning & disinfecting performance criteria, when cleaned and disinfected as labeled.

Animal Study

Not required

Clinical Study

Not required

VIII. CONCLUSION

Stihler Electronic GmbH considers the ASTOPAD Patient Warming System substantially equivalent to the predicate device because they have the same intended use and the same operating principles (warming by convection), any differences between the subject and predicate device do not raise new questions of safety and effectiveness. Testing has been conducted and the subject device meets all requirements of the applicable standards demonstrating that the subject device is substantially equivalent to the predicate device.