DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 14, 2014

Inspiration Healthcare Limited
Wayne Iddon
Regulatory Affairs Manager
Gildor House, West Street
Earl Shilton, Leicester
LE9 7EJ United Kingdom

Re: K140078
Trade/Device Name: TECOTHERM NEO
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: Class II
Product Code: DWJ
Dated: October 13, 2014
Received: October 16, 2014

Dear Mr. Wayne Iddon:

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. 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.

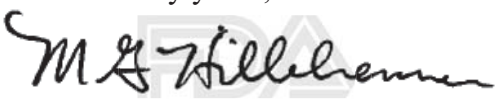
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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); 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 the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

004 Indications for Use Statement

510k number if known: K140078

Device Name: TECOTHERM NEO

Indications for Use:

The TECOTHERM NEO is a temperature management system for pediatric patients, indicated for controlling and monitoring patient's temperature through conductive heat transfer.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Submitter:

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Date of preparation 2013-03

Name of Device: TECOTHERM NEO

Common Name: Whole Body Cooling System

Classification Name: Thermal regulating system
21CFR870.5900
Product Code DWJ

Predicate Devices

K083662	Criticool (Primary)
K071341	Arctic Sun
K024128	Allon Version 5

Device Description
The TECOTHERM NEO is designed for controlled cold & heat treatment procedures and application of specific cold and heat doses to neonate and babies. The system applies cold and heat to total body, body parts and areas depending on therapy target by means of mattresses and/wrap.

The main application is Total Body Treatment of Children up to body mass of 50 kg.

TECOTHERM NEO consists of a unique cold & heat generating device, applied parts like mattresses/wrap, interconnecting hoses (tubing set), accessories. Applied parts are connected to the device via hoses by self- sealing quick-disconnect couplings.

The patient is provided with cold or heat according to the therapy target in a fully controlled way by a circulating fluid. This physiologic safe water- based fluid is cooled or warmed in the device and flows through the mattress or wrap continuously supplying the patient with therapeutically prescribed doses.

Patient temperatures are measured with approved calibrated probes connected to the TECOTHERM NEO device. Temperature data is permanently communicated to the device Operational System.

Circulation of thermalizing fluid to provide cold and heat, accurately reaching set points and operating at set point temperatures accurately with max. deviation of +/-0.3 °C, monitoring the treatment, and alarming when exceeding or falling below temperature limits are performances of TECOTHERM NEO.

TECOTHERM NEO is a system with built-in physiologic closed loop circuit PCLC. TECOTHERM NEO is electronically divided into an **Operational System** and a **Controlling System.** Both sub systems are micro computer (µC) based. Both µC communicate permanently to ensure safe and proper operation according to therapy needs.

A comfortable user MENU will guide the operator to the treatment modes, advise how to proceed the treatment and how to manage treatment details.

Indications for Use

The TECOTHERM NEO is a temperature management system for pediatric patients, indicated for controlling and monitoring patient's temperature through conductive heat transfer.

Comparative Analysis

Enhanced safety by smart design:
In comparison to the predicate devices, TECOTHERM NEO has

- Lowest wattage
- Lowest maximum fluid temperature
- Lowest liquid reservoir
- Lowest fluid flow rate

This is made possible, because the device is designed especially for neonate and pediatric patients. In any fault condition, there is much less chance of hazardous situations – the machine really fits to the needs for the specific treatment and is not “oversized” as it is the case with devices designed for cooling adults.

Listed below are the major attributes of the TECOTHERM NEO compared to the predicate devices listed: Criticool, ArcticSun and Allon 2001 version 5

Specification	**Criticool (primary)**	**Arctic Sun**	**Allon Version 5**	**TECOTHERM NEO**
FDA Notification	**K083662**	**K071341**	**K024128**	**This application**
Control Modes	Automatic	Automatic, manual, Purge, Stop	Automatic	Automatic, Manual, Full treatment program
Heater Capability	500 W	750 W	500 W	340 W
Circulating Fluid	Tap Water	Distilled / Sterile Water	Tap Water	TECOmed Fluid (water based)
Reservoir Capacity	6 liters	5 liters	6 liters	0.25 liters
Heat Exchanger	Garment	Jell Pads	Garment	Polyurethane mattress / wrap
Fluid Flow Rate	1…1.2 l/min	0.5…0.8 l/min	1…1.2 l/min	0.3 l/min 0.5 l/min (max)
Patient Probe Type	YSI 400 Series compatible	YSI 400 Series compatible	YSI 400 Series compatible	YSI 400 Series compatible
Patient Temperature Input	2 – Core and Surface	2	2 – Core and Surface	2 – Core and Surface
Patient Temperature Display Range	18.5…43.9 °C (65.3...111.0 °F) in 0.1 °C/F increments	10…44 °C (50...111.2 °F) In 0.1 °C/F increments	18.5…43.9 °C (65.3...111.0 °F) in 0.1 °C/F increments	10…45 °C (50…113 °F) trusted range: 29...39 °C (84.2…102.2 °F) in 0.1 °C/F increments
Patient Measurement Accuracy	+/- 0.3 °C (0.4 °F)	+/- 0.4 °C @ 10…32 °C +/- 0.2 °C @ 32…38 °C +/-0.4 °C @ 38…44 °C	+/- 0.3 °C (0.4 °F)	+/- 0.3 °C (0.4 °F) 29…39 °C (84.2…102.2 °F) +/- 0.2 °C @ 33.5 °C (@ 92.3 °F)

Specification	Criticool (primary)	Arctic Sun	Allon Version 5	TECOTHERM NEO
Patient Temperature Control Range – Automatic Mode	30…40 °C (86…104 °F) in 0.1 °C/F increments	32…38.5 °C (89.6…101 °F) in 0.1° C/F increments	30…40 °C (86…104 °F) in 0.1 °C/F increments	32…38 °C (89.6…100.4 °F) in 0.1 °C/F increments
Fluid Temperature Display Range	9…44 °C (48.2…111.2 °F) in 0.1 °C/F increments	3…45 °C (37.4…113.0 °F) in 0.1 °C/F increments	9…44 °C (48.2…111.2 °F) in 0.1 °C/F increments	11 °C to 40 °C (51.8…104 °F) in 0.1 °C steps (resolution)
Fluid / Mattress Temperature Control Range – Manual Mode	N/A	4…42 °C (39.2…107.6 °F) in 0.1 °C/F increments	N/A	12…39 °C (53.6…102.2 °F)
Maximum Fluid Temperature (Automatic Mode)	40.8 °C (105.4 °F)	42 °C (107.6 °F)	40.8 °C (105.4 °F)	39 °C (102.2 °F)
Minimum Fluid Temperature	13 °C (55.4 °F)	4 °C (39.2 °F)	13 °C (55.4 °F)	12 °C (53.6 °F)
Mains Input	230/115 VAC, 500 W, 50/60 Hz, 6.3 A	115 VAC, 60 Hz, 11.0A (nominal) 230 VAC, 50 Hz, 5.5 A	230/115 VAC, 500 W, 50/60 Hz, 6.3 A	100…130 V and 200…250 V, 50…60 Hz, max. 350 W,
Leakage Current	< 150 µA	< 300 µA	< 150 µA	< 200 µA (@ 115V) < 400 µA (@ 230V)
Circuit Breaker	2 x 6.3 A fuse	12.0 A	2 x 6.3 A fuse	2 x 250 VAC, S 4A H (@ 100…130 V) S 2.5 A H (@ 200…250 V)
Data Output	Yes	Yes	Yes	Yes
Relative Humidity	10…100%	5…70%	10…100%	10…75%, non-condensing

Specification	Criticool (primary)	Arctic Sun	Allon Version 5	TECOTHERM NEO
(Operating Range)				
Relative Humidity (Storage Range)	10…100%	5…95% non-condensing	10…100%	5…90% non-condensing
Temperature (Operating Range)	10…40 °C (50…104 °F)	10…27 °C (50…80 °F)	10…40 °C (50…104 °F)	5…27 °C (41…80.6 °F)
Temperature (Storage Range)	-40…70 °C (40…158 °F)	-30…50 °C (20…120 °F)	-40…70 °C (40…158 °F)	5…40 °C (41…104 °F) (filled with fluid) -5…60°C (23…140 °C) (without fluid)
Height (without handle)	24.4 inches (620 mm)	30 inches (760 mm)	24.4 inches (620 mm)	7.6 / 8.6 inches 190 / 215 mm
Length	24.6 inches (625 mm)	22 inches (560 mm)	24.6 inches	12.4 inches 310 mm
Width	10.23 inches (260 mm)	12.5 inches (320 mm)	10.23 inches (260 mm)	15 inches 375 mm
Weight (filled)	86 lbs (39 kg)	116 lbs (53 kg)	86 lbs (39 kg)	15.8 lbs 7.2 kg
ALARMS				
High Fluid Temperature	42 °C (107.6 °F)	42.5 / 44 °C (108.5 / 111.2 °F)	42 °C (107.6 °F)	41 °C (105.8 °F)
Low Fluid Temperature	10 °C (50 °F)	3.5 °C (38.3 °F)	10 °C (50 °F)	10 °C (50 °F)
System Patient Temperature High Alarm	38.5 °C (101.3 °F) or 2 °C (3.6 °F) above set point	39.5 °C (103.1 °F)	38.5 °C (101.3 °F) or 2 °C (3.6 °F) above set point	Patient temperature +/- 0.5 °C from target temperature
System Patient Temperature Low Alarm	35.5 °C (95.9 °F) or 0.5 °C (0.9 °F) below set point	31.0 °C (87.8 °F)	35.5 °C (95.9 °F) or 0.5 °C (0.9 °F) below set point	Patient temperature +/- 0.5 °C from target temperature
Adjustable Patient	N/A	10.1…44 °C (50.1…111.2	N/A	N/A

Specification	Criticool (primary)	Arctic Sun	Allon Version 5	TECOTHERM NEO
Temperature High Alarm		°F)		
Adjustable Patient Temperature Low Alarm	N/A	10.0…41.9 °C (50…107.5 °F)	N/A	N/A
Patient Probe Fault Alarm (short or open)	Yes	Yes	Yes	Yes
Fluid Flow Alarm	Yes	Yes	Yes	Yes
Fluid Temperature High Alarm	42.0 °C (107.6 °F)	43.0 / 44 °C (109.4 °F / 111.2 °F)	42.0 °C (107.6 °F)	41.0 °C (105.8 °F)
Fluid Temperature Low Alarm	10 °C (50 °F)	3.0 °C (37.4 °F)	10 °C (50 °F)	10 °C (50 °F)
Reservoir Low Alarm	Yes	Yes	Yes	Yes
System Self Test Alarm on Power Up	Yes	Yes	Yes	Yes

The Tecotherm Neo has the same intended use as the predicates (albeit only for pediatrics) and similar technological characteristics that do not raise new types of questions of safety and effectiveness and is therefore substantially equivalent to the predicate devices.

Performance Testing

The Tecotherm Neo device was introduced into the European market in 2010.

Materials were tested and proven for biocompatibility.

The design of the device has been verified and validated both through testing and actual experience throughout Europe.

The system was tested and proven for durability under transport conditions by an independent third party. Subsequent functional and performance testing was performed and showed no deterioration in the device integrity.

Reports of the above are confidential but were included with this submission as requested. The testing and European experience provided data that demonstrated substantial equivalence to the predicates.

The therapy type has been proven in the Europe wide Toby trial. This report can be viewed using the following URL:

http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0038504 .

Conclusion

The data from using the device show the high performance level regarding safety and effectiveness. The device is substantially equivalent to the predicate devices.