DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 3, 2017

Brain Cool Ab
% Adam Harris
Associate Director Regulatory Affairs
Target Health Inc.
261 Madison Ave
New York, New York 10016

Re: K162523
Trade/Device Name: The IQool System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: NZE
Dated: March 31, 2017
Received: April 3, 2017

Dear Adam Harris:

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" (21 CFR 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,

Fernando Aguel -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162523

Device Name
The IQool System

Indications for Use *(Describe)*
Temperature reduction for adult patients where clinically indicated, e.g. in hyperthermic patients.

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

510(k) Applicant

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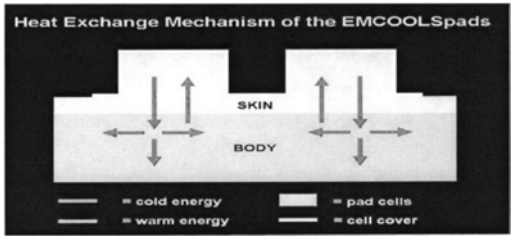
Date of Summary: April 28, 2017

Device Proprietary Name	The IQool™ System		
Common/Usual Name	Thermal Regulating System		
Classification Names / Numbers and Code	**21 CFR**	**Classification Name**	**Code**
	870.5900	Thermal Regulating System	NZE
Regulatory Class	II		
Prescription Status	Prescription Device		
Classification Panel	Cardiovascular		
Predicate Device	K100071	EMCoolspad	
Reference Device	K101092	Arctic Sun® Temperature Management System	
Description of Device	The IQool™ System is a surface cooling device that sustains and monitors patient temperature within a range of 33°C to 37°C. The IQool™ System consists of: • ECU 100 – refrigeration and control unit – The ECU 100 is a refrigerator unit with an integrated control system operated via a touch screen monitor. • BC COOL- BC COOL is a cooling liquid consisting of diluted monopropylene glycol (MPG5). The dilution is made by BrainCool AB to optimally serve the IQool™ System. Five liters of BC COOL are delivered with the system. • Cooling Pads – the single use cooling pads are the only skin contacting component and can be fitted to the head/neck, torso, and thigh. Liquid coolant is circulated from the tank		

	through the pads to cool patients. The cooling pads are designed and molded to give a good fit during treatment and are intended for single patient use. • Stabilization insulation – The patented stabilization insulation is made of insulating and moisture-absorbent neoprene. The stabilization insulation supports the cooling pads and insulates against the ambient environment condensation. The elasticity of the stabilization insulation keeps the Cooling Pads in place during treatment and ensures maximum cooling between the skin and the surface of the Cooling Pad. The stabilizing insulation is intended for single use only. Accessories: • BC STICK — The BC STICK is a USB flash drive used to save system configurations, specifically prepared to communicate with the program of the IQool™ System. The BC stick does not store or capture any user identifying information. It can also be used to save a log file for system troubleshooting or to update the software. • Filling pitcher – The filling pitcher is for refilling the tank with BC COOL (coolant). Fill the tank with coolant before or directly after start to avoid damage to the system. The ECU 100 pushes temperature-controlled BC COOL ranging between 4°C and 30°C through the Cooling Pads at approximately 1.2 liter per minute per pad. This results in heat exchange between the BC COOL and the patient. Patient temperature is monitored by one or two commercially available third-party temperature probes. The IQool™ System maintains a controlled patient temperature during the entire treatment period. Any deviations from the default temperature are automatically adjusted by the system. The default treatment settings for temperature and time can be changed through the touchscreen monitor. Alarms and notifications are activated if any errors are detected. Temperature graphs for each treatment are shown on the touchscreen display for visual monitoring.
Indications for Use	Temperature reduction in adult patients where clinically indicated, e.g. in hyperthermic patients.

Table: Substantial Equivalence Comparison Table

Name	IQool™ Thermal Regulation System	EMCoolspad – Predicate	Arctic Sun® Temperature Management System - Reference
Manufacturer	**BrainCool AB**	**Emergency Medical Cooling Systems AG**	**Medivance, Inc**
510(K) Number	K162523	K100071	K101092
Product Code	NZE	NZE	DWJ
Regulation	21 CFR 870.5900	21 CFR 870.5900	21 CFR 870.5900
Indications for Use	Temperature reduction for adult patients where clinically indicated, e.g. in hyperthermic patients.	Temperature reduction for adult patients where clinically indicated, e.g. in hyperthermic patients.	Thermal regulating system, indicated for monitoring and controlling patient temperature.
Description	The IQool System is a surface cooling device that sustains and monitors patient temperature within a range of 33°C to 37°C. The IQool™ System consists of: • ECU 100 – refrigeration and control unit – The ECU 100 is a refrigerator unit with an integrated control system operated via a touch screen monitor. • BC COOL- BC COOL is a cooling liquid consisting of diluted monopropylene glycol (MPG5). The dilution is made by BrainCool AB to optimally serve the IQool™ System. Five	The EMCOOLSpad is a single use surface (skin) cooling device, which is adherent to the patient's skin and so highly adjustable during the cooling procedure. An EMCOOLSpad consists of multiple cooling-cells made of thermoplastic polyurethane, filled with high thermal conductivity material, stored frozen at 0 to -l0°C. **Physics and Mechanism Summary** In nature, there is always an automatically started balancing-process among interacting Subjects, this process stops automatically when a perfectly balanced energy level is reached. For the EMCOOLSpad and the patient	The Arctic Sun Temperature Management System is a thermoregulatory device that monitors and controls patient temperature within a range of 32.0° C to 38.5° C (89.60° F to 101.3° F). The Arctic Sun System consists of the Arctic Sun Control Module and disposable ArcticGel Pads. A patient temperature probe connected to the Control Module provides patient temperature feedback to an internal control algorithm which automatically increases or decreases the circulating water temperature to achieve a pre-set patient target temperature determined by the clinician.

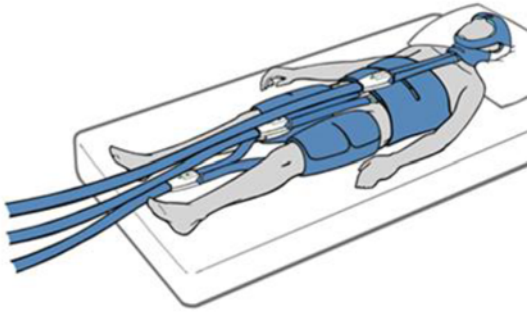
	liters of BC COOL are delivered with the system. • Cooling Pads – the single use cooling pads are the only skin contacting component and can be fitted to the head/neck, torso, and thigh. Liquid coolant is circulated from the tank through the pads to cool patients. The cooling pads are designed and molded to give a good fit during treatment and are intended for single patient use. • Stabilization insulation – The patented stabilization insulation is made of insulating and moisture-absorbent neoprene. The stabilization insulation supports the cooling pads and insulates against the ambient environment condensation. The elasticity of the stabilization insulation keeps the Cooling Pads in place during treatment and ensures maximum cooling between the skin and the surface of the Cooling Pad. The stabilizing insulation is intended for single use only. Accessories:	this interaction process is started automatically when the pads are adhered to the skin (see sketch below) and ends automatically with a balanced energy level between cold pad and warm skin. If you remove EMCOOLSpad from the patient's body, another balancing-process commences automatically, leading to a slow and mild re-warming, again to a certain "balanced level".  Between start-point and end-point of this balancing process, the cold goes into the skin vertically and locally first, but immediately is "transported" away into the complete human body and cools it down. Seen from the patient's perspective the warmth of the body and skin is "transported" into the pad and melts it. **User and Patient Interface** The patient's core temperature is regulated within in a certain temperature range by manually	The Arctic Sun pulls temperature-controlled water ranging between 40C and 420C (39.20F and 1 07.60F) through the ArcticGel Pads, resulting in heat exchange between the water and the patient.

	• BC STICK — The BC STICK is a USB flash drive used to save system configurations, specifically prepared to communicate with the program of the IQool™ System. The BC stick does not store or capture any user identifying information. It can also be used to save a log file for system troubleshooting or to update the software. • Filling pitcher – The filling pitcher is for refilling the tank with BC COOL (coolant). Fill the tank with coolant before or directly after start to avoid damage to the system. The ECU 100 pushes temperature-controlled BC COOL ranging between 4°C and 30°C through the Cooling Pads at approximately 1.2 liter per minute per pad. This results in heat exchange between the BC COOL and the patient. Patient temperature is monitored by one or two commercially available third-party temperature probes. The IQool™ System maintains a controlled patient temperature during the entire treatment period. Any deviations from the default temperature are automatically adjusted	removing (= warming) or applying (=cooling) the EMCOOLSpad. **Device Interface** A commercially available third-party temperature probe connected to a commercially available third-party monitor senses the patient's core temperature.	

	by the system. The default treatment settings for temperature and time can be changed through the touchscreen monitor. Alarms and notifications are activated if any errors are detected. Temperature graphs for each treatment are shown on the touchscreen display for visual monitoring.		
Technological Characteristics	Achieves cooling with patient contacting Cooling Pads through which coolant is circulated. Cooling is controlled by the settings on the device. Consistent temperature reduction is maintained and controlled by the system pushing more or less coolant through the pads as needed achieve or maintain desired cooling.	Achieves cooling through patient contacting Cooling Pads which are filled with a high thermal conductivity material. Pads must be pre-cooled before use. To control cooling, pads are removed from the patient's skin to slow cooling or to stop cooling. The pads are re-applied to the patient's skin to recommence the cooling process.	Achieves cooling and heating through patient contacting Cooling Pads through which water is circulated.
Therapy Modes	Hypothermia: Cool Patient Normothermia: Control Patient	Cooling patients to desired temperature through manually removing and reapplying the pads	Normothermia: Control Patient Hypothermia: Cool Patient, Rewarm Patient
Cooling Mechanism	Employs a single tank which employs three solenoid valves (ON/OFF) to push coolant to the pads intermittently to achieve and maintain desired temperature automatically.	Cooling Pads are filled with a high thermal conductivity material and pre-frozen at 0 to -l0°C**.**	Employs two separate tanks, one for cooling and another for heating. To obtain a certain temperature liquid from the two tanks is mixed passes continuously into the cooling pads on the patient.
Heating Mechanism	None	None	Yes
Cooling Rates	1.38 to 1.61 °C/hour	0.6 °C/hour to 3.3 °C/hour	1.2 to 2.0 per hour °C/hour

Other Specifications

Cooling medium	Diluted monopropylene glycol	HypoCarbon® - described as a high thermal conductivity material	Water
Reservoir Capacity	4.0 liters	N/A	3.5 liters
Water Flow Rate	1.5 – 6 liters per minute	N/A	5 liters per minute
Patient Probe Type	YSI 400 Series compatible (rectal)	YSI 400 Series compatible	YSI 400 Series compatible
Patient Temperature Inputs	Patient Temp 1: control, monitor, alarm Patient Temp 2: monitor, alarm	N/A	Patient Temp 1: control, monitor, alarm Patient Temp 2: monitor, alarm
Patient Temperature Measurement Accuracy	±0.4°C (10°C to 32°C) ±0.2°C (32°C to 38°C) ±0.4°C (38°C to 44°C) Includes ±°0.1C external probe	N/A	±0.4°C (10°C to 32°C) ±0.2°C (32°C to 38°C) ±0.4°C (38°C to 44°C) Includes ±°0.1C external probe
Patient Temperature Range	33°C to 37°C 91.4°F to 98.6°F 0.1 °C/°F increments	N/A	32°C to 38.5°C 89.6°F to 101.3°F 0.1 °C/°F increments
Water/Fluid Temperature Display Range	-50°C to 99°C / -58°F to 210.2°F 0.1 °C/°F increments	N/A	-50°C to 99°C / -58°F to 210.2°F 0.1 °C/°F increments
Water Temperature Control Range (Manual)	-12°C to 27°C / 10.4°F to 80.6°F 0.1 °C/°F increments	N/A	4°C to 42°C / 39.2°F to 107.6°F 0.1 °C/°F increments
Mains Input	115 VAC, 60 Hz, 10.0 Amp (nominal) 230 VAC, 50 Hz, 6.3 Amp	N/A	115 VAC, 60 Hz, 11.0 Amp (nominal) 230 VAC, 50 Hz, 5.5 Amp
Alarms	Monitoring and safety alarms	None	Monitoring and safety alarms

Pad Placement	 Total of 4 pads, 2 pads for the thighs, 2 for the torso, plus 2 optional pads to cover the head and neck for additional cooling area coverage.		
Dimensions	Height: 41 inches (105.2 cm) Width: 20 inches (50.5cm) Depth: 24 inches (61 cm)	Not listed in labeling	Height: 35 inches (89 cm) Width: 14 inches (36 cm) Depth: 18.5 inches (47 cm)
Weight	Empty: 71 kg / 157 lbs. Filled: 75 kg / 165 lbs.	Not listed in labeling	Empty: 43 kg / 95 lbs. Filled: 47 kg / 103 lbs.

Summary of Technological Characteristics compared to the predicate device

Characteristics	**IQool™ Thermal Regulation System K16**	**EMCoolspad K100071**	**Arctic Sun® Temperature Management System K101092**
Thermal regulating system	Yes	Yes	Yes
Non-invasive system	Yes	Yes	Yes
Patient surface cooling	Yes	Yes	Yes
Contact to the patient's skin during cooling	Yes	Yes	Yes
Single use device	Yes	Yes	Yes
Temperature gradient between patient and cooling pad	Yes	Yes	Yes
Removal of thermal energy from the patient	Yes	Yes	Yes
Rapid cooling function	No	Yes	No
Temperature monitoring with a temperature probe	Yes	Yes	Yes
Heating mechanism	No	No	Yes

Comparison of Significant Features

- With the Predicate and Subject devices, cooling pads are single use and placed on the patient's chest arms and legs.
- The cooling pads on both devices transfer cooling to the patient and are monitored by 3rd party temperature probes.
- The Predicate device manages patient temperature (by manually removing the cooling pads or applying the cooling pads), whereas the Subject device manages the patient temperature and the cooling process automatically according to settings.
- Cooling rates are comparable but not exactly the same for the Predicate and Subject devices

Discussion

The IQool System is not a new device from a standpoint of intended use or of technological characteristics. The intended use and indications for use for the Subject and Predicate devices are the same. Both devices are applying cooling to the patient at the same location on the body. The main differences are the energy source for the Subject device is electrical and clinicians can manage cooling with the touch screen settings of the device, whereas with the Predicate device, the user must manage cooling manually by applying and removing the pads to achieve the desired level of cooling. The Predicate cooling pads are stored frozen at 0 to -l0°C which is

considerably colder than the coolant in the IQool, which ranges in temperature from +4 to 30°C. This difference in temperature and approach to the cooling process may mean that the Predicate can cool at a faster rate than the Subject device, but that the Subject device may be better tolerated, and with the Subject device there may be a lower risk of over cooling a patient.

Performance Data

Testing was completed for the IQool™ System which demonstrated intended, labeled device performance. Performance testing included functional testing, temperature testing, temperature control, cooling pads, full software testing, shipping and handling, and climate testing, biocompatibility testing for patient contacting parts, and standards testing including electrical safety, electromagnetic compatibility, usability, alarm systems, and microbiological testing for the coolant. All testing confirmed that the IQool™ System operates as described and is substantially equivalent to the predicate device.

The IQool™ System was tested to conform to the following standards:

- IEC/EN 60601-1:2005 ed 3.1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC/EN 60601-1-2:2007 ed. 3 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC/EN 60601-1-6:2010 ed. 3 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC/EN 60601-1-8:2006 ed. 2 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC/EN 62304:2007 ed. 1 Medical device software - Software life-cycle processes
- IEC/EN 50581:2014 ed. 1 Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
- ASTM-D4169 Standard Practice for Performance Testing of Shipping Containers and Systems
- IEC-TR 60721-4-7 Classification of environmental conditions – Part 4-7: Guidance for the correlation and transformation of environmental condition classes of IEC 60721-3 to the environmental tests of IEC 60068 - Portable and non-stationary use
- ISO 14971:2012 ed. 4 Medical devices - Application of risk management to medical devices
- ISO 13485:2012 ed. 3 Medical devices

Conclusion

It is the opinion of the Sponsor that the IQool™ System does not raise new questions of safety and effectiveness in comparison to the Predicate. The differences in technological characteristics between the IQool™ System and the Predicate are not critical and thus meet the requirements of 21 CFR 807.87(f). Therefore, the sponsor has determined that the IQool™ System is substantially equivalent to its Predicate EMCoolspad K100071.