May 18, 2018

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

Re: K180375
Trade/Device Name: The IQoolTM Warm System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: Class II
Product Code: DWJ
Dated: March 28, 2018
Received: March 30, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole G. Ibrahim -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180375

Device Name
The IQoolTM Warm System

Indications for Use *(Describe)*
The IQoolTM Warm System is a temperature regulating system indicated for monitoring and controlling patient temperature.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(k) Summary

510(k) Applicant

Brain Cool AB

Scheelevägen 2, Medicon
Village Lund, Sweden SE-223
81

Phone: +46 733 93 70 76

Contact Person:

Adam Harris, MM, RAC
Associate Director, Regulatory Affairs
Target Health Inc.
261 Madison Avenue, 24th Floor
New York, NY 10016

Telephone: (646) 218-2009
Fax: (212) 682-2105
aharris@targethealth.com

Date of Summary: March 28, 2018

Device Proprietary Name	The IQool™ Warm System		
Common/Usual Name	Thermal Regulating System		
Classification Names / Numbers and Code	**21 CFR**	**Classification Name**	**Code**
	870.5900	Thermal Regulating System	DWJ
Regulatory Class	II		
Prescription Status	Prescription Device		
Classification Panel	Cardiovascular		
Predicate Device	K101092	Arctic Sun® Temperature Management System	
Description of Device	The IQool™ Warm System is a non-invasive, thermal regulating system that monitors and controls patient temperature within a range of 32°C to 38.5°C (89.6°F to 101.3°F). The IQooL™ Warm System consists of: • ECU 100 – refrigeration and control unit – an integrated control system operated via a touch screen monitor. • BC COOL– a cooling liquid consisting of diluted monopropylene glycol (MPG5). The dilution is made by		

	BrainCool AB to optimally serve the IQool™ Warm System. Five liters of BC COOL are delivered with the system. • Cooling Pads – the single use 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 control patient temperature. The 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-absorbing neoprene which 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 contact between the skin and the surface of the cooling pad. The stabilizing insulation is intended for single use only. Accessories: • BC Stick – a USB flash drive used to save system configurations, specifically prepared to communicate with the program of the IQool™ Warm 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 – 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 40°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™ Warm System maintains a controlled patient temperature during the entire treatment period. Any deviations from the set temperature are automatically re-adjusted by the system. The 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	The IQool™ Warm System is a temperature regulating system indicated for monitoring and controlling patient temperature.

Table 1: Substantial Equivalence Comparison Table

Name	IQool™ Warm System	Arctic Sun® Temperature Management System – Predicate	IQool™ System – Reference
Manufacturer	**BrainCool AB**	**Medivance, Inc**	**BrainCool AB**
510(K) Number	K180375	K101092	K162523
Product Code	DWJ	DWJ	NZE
Regulation	21 CFR 870.5900	21 CFR 870.5900	21 CFR 870.5900
Indications for Use	The IQool™ Warm System is a temperature regulating system indicated for monitoring and controlling patient temperature.	Thermal regulating system, indicated for monitoring and controlling patient temperature.	Temperature reduction for adult patients where clinically indicated, e.g. in hyperthermic patients.
Description	The IQool™ Warm System is a non-invasive, thermal regulating system that monitors and controls patient temperature within a range of 32°C to 38.5°C (89.6°F to 101.3°F). The IQool™ Warm System consists of: • ECU 100 refrigeration and control unit – an integrated control system operated via a touch screen monitor. • BC COOL – a cooling liquid consisting of diluted monopropylene glycol (MPG5). The dilution is made by BrainCool AB to optimally serve the IQool™ Warm System. Five liters of BC	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. The Arctic Sun pulls temperature-	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™

Name	IQool™ Warm System	Arctic Sun® Temperature Management System – Predicate	IQool™ System- Reference
	COOL are delivered with the system. • Cooling Pads – the single use 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 control patient temperature. The 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-absorbing neoprene which 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 contact between the skin and the surface of the cooling pad. The stabilizing insulation is intended for single use only.	controlled water ranging between 4° C and 42 ° C (39.2° F and 107.6° F) through the ArcticGel Pads, resulting in heat exchange between the water and the patient.	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

Name	IQool™ Warm System	Arctic Sun® Temperature Management System – Predicate	IQool™ System – Reference
	Accessories: • BC Stick – a USB flash drive used to save system configurations, specifically prepared to communicate with the program of the IQool™ Warm 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 – for refilling the tank with 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 40°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™ Warm System maintains a controlled patient temperature during		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

Name	IQool™ Warm System	Arctic Sun® Temperature Management System – Predicate	IQool™ System- Reference
	the entire treatment period. Any deviations from the set temperature are automatically re-adjusted by the system. The 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.		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.
Technological Characteristics	Achieves thermal regulation (cooling and rewarming) by circulating liquid coolant through patient contacting cooling pads. Temperature is controlled by the settings on the device.	Achieves cooling and heating through patient contacting gel pads through which water is circulated. Temperature is controlled by the settings on the device.	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.
Therapy Modes	Hypothermia: cool, maintain Normothermia: actively rewarm	Hypothermia: cool, maintain Normothermia: actively rewarm	Hypothermia: cool, maintain Normothermia: monitor and control rewarming
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.	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	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.

Name	IQool™ Warm System	Arctic Sun® Temperature Management System – Predicate	IQool™ System- Reference
		the patient.	
Heating Capability	Yes	Yes	No
Heating Capacity	2500 BTU/hr 750 Watts	2500 BTU/hr / 750 Watts	N/A
Cooling Rates	1.38 to 1.61 °C/hour	1.2 to 2.0 per hour °C/hour	1.38 to 1.61 °C/hour

Other Specifications

Cooling medium	Diluted monopropylene glycol	Water	Diluted monopropylene glycol
Reservoir Capacity	4.0 liters	3.5 liters	4.0 liters
Water Flow Rate	1.5 – 6 liters per minute	5 liters per minute	1.5 – 6 liters per minute
Patient Probe Type	YSI 400 Series compatible (rectal)	YSI 400 Series compatible	YSI 400 Series compatible (rectal)
Patient Temperature Inputs	Patient Temp 1: control, monitor, alarm Patient Temp 2: monitor, alarm	Patient Temp 1: control, monitor, alarm Patient Temp 2: monitor, alarm	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	±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	±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	32°C to 38.5°C 89.6°F to 101.3°F 0.1 °C/°F increments	32°C to 38.5°C 89.6°F to 101.3°F 0.1 °C/°F increments	33°C to 37°C 91.4°F to 98.6°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	-50°C to 99°C / -58°F to 210.2°F 0.1 °C/°F increments	-50°C to 99°C / -58°F to 210.2°F 0.1 °C/°F increments
Water	4°C to 40°C / 39.2°F to 105.8°F	4°C to 42°C / 39.2°F to 107.6°F	4°C to 30°C / 39.2°F to 86°F

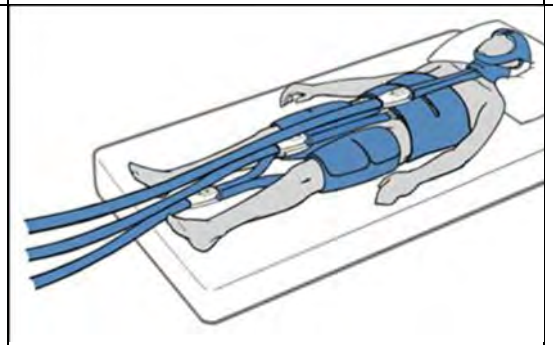
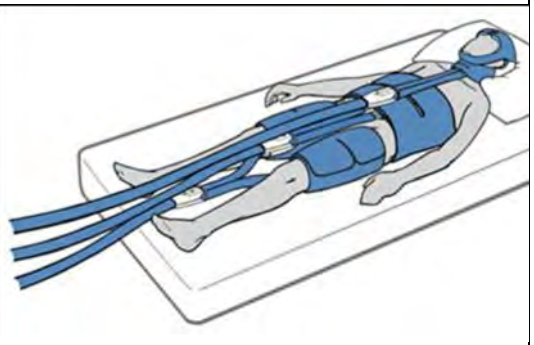
Temperature Control Range (Manual)	0.1°C / 0.1°F increments	0.1 °C/°F increments	0.1 °C/°F increments
Mains Input	115 VAC, 60 Hz, 10.0 Amp (nominal) 230 VAC, 50 Hz, 6.3 Amp	115 VAC, 60 Hz, 11.0 Amp (nominal) 230 VAC, 50 Hz, 5.5 Amp	115 VAC, 60 Hz, 10.0 Amp (nominal) 230 VAC, 50 Hz, 6.3 Amp
Alarms	Monitoring and safety alarms	Monitoring and safety alarms	Monitoring and safety alarms
Alarm if patient warms too quickly	Yes	No	N/A
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.		 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)	Height: 35 inches (89 cm) Width: 14 inches (36 cm) Depth: 18.5 inches (47 cm)	Height: 41 inches (105.2 cm) Width: 20 inches (50.5cm) Depth: 24 inches (61 cm)
Weight	Empty: 73 kg / 161 lbs. Filled: 77 kg / 169 lbs.	Empty: 43 kg / 95 lbs. Filled: 47 kg / 103 lbs.	Empty: 71 kg / 157 lbs. Filled: 75 kg / 165 lbs.
Usage in OR	Not intended to be used in OR	N/A	Not intended to be used in OR
Component sterilization	Not Sterilized	N/A	Not Sterilized
Cooling pads shelf-life (Torso, Neck and Thighs)	2 Years	N/A	2 Years

Table 2: Summary of Technological Characteristics Compared to the Predicate Device

Characteristics	IQool™ Warm System K180375	Arctic Sun® Temperature Management System K101092	IQool™ System K162523
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 treatment	Yes	Yes	Yes
Single use device	Yes	Yes	Yes
Temperature gradient between patient and pads	Yes	Yes	Yes
Removal of thermal energy from the patient	Yes	Yes	Yes
Temperature monitoring with a temperature probe	Yes	Yes	Yes
Heating mechanism	Yes	Yes	No

Comparison of Significant Features

- The Predicate and the Subject devices are identical in intended use and technological characteristics.
- Cooling and rewarming rates for both the Predicate and Subject devices are comparable and are according to standard practice in therapeutic hypothermia treatment.
- For both 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.
- Minor differences include dimensions, number of cooling tanks, flow rate, cooling and warming rates and the Subject device includes an additional alarm in case the patient begins warming too quickly.

Discussion

Both Subject and Predicate devices have the same intended use and there are no significant differences in technological characteristics between the Subject and Predicate devices. For this submission, the sponsor submitted bench testing for the new rewarming features and cross-referenced information from the reference device (K162523) which have not change as a result of adding rewarming capability. For both Subject and Predicate, temperature is managed by circulating fluid through surface-contacting pads, and for both, temperature is monitored

through one or two 3rd-party temperature probes. Both systems provide monitoring and safety alarms. The Subject device includes an additional alarm in case the patient begins warming too quickly.

The simulated testing submitted for the Subject device demonstrated cooling patients to hypothermia, maintaining patient temperature and rewarming patients to normothermia comparably to the Predicate device based on published cooling times for the Predicate and according to general therapeutic hypothermia practice as represented in published research. This testing supported substantial equivalence in that the Subject device accomplished the same intended use as the Predicate with the same or similar technological characteristics.

In addition, the cooling pads and all accessories identified in this device will be identical in terms of design, material, etc. to those of the previously cleared IQool system K162523 and both devices are not intended to be used in the operating room (OR). Thus, the previously provided shelf-life and sterilization information presented in K162523 will be applicable for the IQool Warm System K180375. Additionally, the Sponsor submitted no new Biocompatibility testing for K180375, as the patient contacting materials are identical to those cleared in K162523. A new software testing and package were provided in this submission for the Subject device K180375 appropriate to the identified level of concern according to the FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.*

Conclusion

It is the opinion of the Sponsor that the IQool™ Warm System does not raise new questions of safety and effectiveness in comparison to the Predicate. This is supported by the comparison table above and the cited Reference device. The differences between the IQool Warm System and the Predicate are minor and thus meet the requirements of 21 CFR 807.87(f). Therefore, the sponsor has determined that the IQool™ Warm System is substantially equivalent to the Predicate, Arctic Sun Temperature Management System K101092.