October 4, 2023

BrainCool AB
% Adam Harris
Senior Director, Regulatory and Strategic Development
Target Health LLC
450 Commerce Boulevard
Carlstadt, New Jersey 07072

Re: K232844
Trade/Device Name: The IQool System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: September 12, 2023
Received: September 14, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Kalkidan Molla -S

for Nicole Gillette
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: 06/30/2023
*See PRA Statement below.*

Submission Number *(if known)*

K232844

Device Name

The IQool™ System

Indications for Use *(Describe)*

The IQool System is a thermal 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.***

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# 5. 510(k) Summary

## 5.1 Sponsor Information

Brain Cool AB
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## 5.2 Contact Person

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## 5.3 Date of Summary

October 2, 2023

## 5.4 Device Name and Classification

| **Common or Usual Name** | **Targeted Temperature Management System (TTM)** |
|---|---|
| Proprietary Name | The IQool™ System |
| Classification Name | Thermal regulating system (21 CFR § 870.5900) |
| Device Classification | Class II |
| Product Code | DWJ |

## 5.5 Predicate Device/Reference Device

- Predicate Device – K180375 IQool™ Warm System
- Reference Device - K200225 Arctic Sun (for the addition of alarm to protect skin from extended cooling exposure)

## 5.6 Description of Device

The IQool™ System is a non-invasive, thermal regulating system that monitors and controls patient temperature within a range of 33°C to 38.5°C (91.4°F to101.3°F).

The IQooL™ 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™ System. Five liters of BC COOL are delivered with the system.

- Cooling Pads – The Cooling Pads are made of non-sterile, biocompatible material and do not contain latex. The Cooling Pads are intended for single use only.

- Stabilization Insulation – The patented stabilization insulation is made of insulating and moisture-absorbent neoprene. It insulates against the ambient environment while counteracting condensation. The elasticity of the stabilization insulation keeps the Cooling Pad 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™ 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 should be used to fill or refill the coolant tank. Fill the tank with coolant before or directly after starting to enable start of the system.

The IQool™ System is a thermoregulatory device that monitors and controls patient temperature within a range of 33°C to 38.5°C. The IQool System refrigeration and control unit (ECU 100) pushes a temperature-controlled cooling agent (BC COOL), ranging between 4°C and 40°C, through the Cooling Pads applied to the patient. This results in heat exchange between the BC COOL and the patient. Patient core temperature is monitored and controlled based on the temperature probe (PT1) attached to the system. The IQool™ System maintains a controlled patient temperature during the entire treatment period. The default treatment settings for temperature and time can be changed via 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. After a treatment, a detailed log file can be collected with the memory stick (BC STICK).

## 5.7 Indications for Use

The IQool™ System is a thermal regulating system indicated for monitoring and controlling patient temperature.

## 5.8 Comparative Data for Determining Substantial Equivalence of the New Device to the Predicate Device

Information provided in this 510(k) submission for software changes documents that the IQool™ System has the same technologicalcharacteristics (i.e., same design, materials and energy source) as the predicate device. In addition, the testing summaries provided document that the changes were verified and that the subject device provides the same temperature management performance and safety as the predicate device.

## 5.9 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. This is supported by the equivalence and comparison information, and the data summaries presented. The differences in technological characteristics between the IQool™ System and the Predicate meet the requirements of 21 CFR 807.87(f). Therefore, the sponsor has determined that the updated IQool™ System is substantially equivalent to its Predicate, IQool™ Warm System K180375.