March 29, 2022

BrainTemp, Inc.
℅ Sally Maher
Regulatory Consultant
P.O. Box 823
Bryn Mawr, PA 19010

Re: DEN200042
Trade/Device Name: BrainTemp Neonate (BTNeo) System
Regulation Number: 21 CFR 882.1565
Regulation Name: Brain temperature measurement system
Regulatory Class: Class II
Product Code: QSL
Dated: June 16, 2020
Received: June 26, 2020

Dear Sally Maher:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the BrainTemp Neonate (BTNeo) System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The BTNeo System is indicated for measurement of a neonate's brain temperature. The brain temperature may be displayed with a compatible vital sign monitor system and is intended to be displayed along with core temperature.
>
> The BTNeo System is indicated for use by qualified healthcare professionals that care for neonates (from birth through the first 28 days of life) in intensive care units, operating rooms, and recovery rooms.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the BrainTemp Neonate (BTNeo) System, and substantially equivalent devices of this generic type, into Class II under the generic name brain temperature measurement system.

FDA identifies this generic type of device as:

> **Brain temperature measurement system**. A brain temperature measurement system is an externally placed, prescription device intended to measure brain temperature.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE)

determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On June 26, 2020, FDA received your De Novo requesting classification of the BrainTemp Neonate (BTNeo) System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the BrainTemp Neonate (BTNeo) System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the BrainTemp Neonate (BTNeo) System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks to health are inaccurate measurement made by the device, resulting in misuse or misinterpretation of device output; equipment malfunction leading to injury to user/patient (shock, burn); and adverse tissue reaction, including thermal or pressure injuries. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks to Health	Mitigation Measures
Inaccurate measurement made by the device, resulting in misuse or misinterpretation of device output	In vivo performance testing Non-clinical performance testing Software verification, validation, and hazard analysis Usability evaluation Labeling
Equipment malfunction leading to injury to user/patient (e.g., shock, burn, interference)	Electrical, mechanical and thermal safety testing Electromagnetic compatibility (EMC) testing Labeling
Adverse tissue reaction, including thermal or pressure injuries	Biocompatibility evaluation Usability evaluation Labeling

In combination with the general controls of the FD&C Act, the brain temperature measurement system is subject to the following special controls:

(1) In vivo performance testing must demonstrate that the device performs as intended for its anticipated conditions of use and can accurately and reliably measure brain temperature compared to a ground truth measurement.

(2) Non-clinical performance testing must demonstrate that the device can accurately measure changes in brain temperature under simulated conditions of use. Testing must assess repeatability within pre-

specified, clinically relevant parameters. The technical specifications of the device's hardware and software must be fully characterized.

(3) Electrical safety, thermal safety, mechanical safety, and electromagnetic compatibility (EMC) testing must be performed.

(4) Software documentation must include a detailed technical description of the algorithm(s) used to generate the device output(s), and be accompanied by verification and validation testing to ensure device and algorithm functionality as informed by the software requirements and hazard analysis.

(5) The tissue contacting device components must be demonstrated to be biocompatible.

(6) Usability evaluation must demonstrate that the intended user(s) can safely and correctly use the device, based solely on reading the directions for use.

(7) Labeling must include:
   (i) Instructions for use, including a detailed description of the device and explanation of all device outputs.
   (ii) The following warnings:
      (A) A statement that the device is not intended to measure core body temperature, and to use an independent thermometer to measure core body temperature.
      (B) Conditions of use that may impact the accuracy and reliability of the device measurement.
      (C) Conditions of use that may affect skin integrity or cause skin injury, such as extended wear duration or placement of the device on damaged or compromised skin, skin lesions, or open wounds.
      (D) Limitations of device use to inform diagnosis or therapy.
   (iii) Summaries of in vivo testing conducted to demonstrate how the device functions as intended. The summary must include the following:
      (A) A description of each device output.
      (B) A description of the study population and the use environment.
      (C) The methods used to collect temperature data.
      (D) Any observed adverse events and complications.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a

premarket notification containing information on the brain temperature measurement system they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Mohua Choudhury at 240-402-3095.

Sincerely,

Christopher Loftus -S

Digitally signed by Christopher Loftus -S
Date: 2022.03.29 16:22:26 -04'00'

Christopher M. Loftus, MD, FAANS
Acting Director
OHT5: Office of Neurological
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