August 16, 2023

Hadleigh Health Technologies
% Allison Komiyama
Consultant
Rqm+
2251 San Diego Ave
Suite B-257
San Diego, California 92110

Re: K230298
Trade/Device Name: Celsi Monitor
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: July 17, 2023
Received: July 18, 2023

Dear Allison Komiyama:

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. 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 located 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.

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) 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 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 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,

Porsche Bennett

Porsche Bennett
For David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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.

510(k) Number *(if known)*
K230298

Device Name
Celsi Monitor

Indications for Use *(Describe)*
Celsi Monitor is intended for use in hospitals under a clinician's supervision or at their direction to assist nurses in continuous temperature monitoring of neonates. The device measures abdominal skin temperature through direct contact.

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
K230298

DATE PREPARED
August 16, 2023

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DEVICE INFORMATION

Proprietary Name/Trade Name:	Celsi Monitor
Regulation Name:	Clinical Electronic Thermometer
Regulation Number:	21 CFR 880.2910
Regulation Class:	Class II
Product Code:	FLL
Premarket Review:	Drug Delivery and General Hospital Devices, and Human Factors (DHT3C)
Review Panel:	General Hospital

PREDICATE DEVICE IDENTIFICATION
The Celsi Monitor is substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K083185	Cadi SmartSense Wireless Temperature Monitoring System / Cadi Scientific Pte. Ltd	✓

DEVICE DESCRIPTION

Celsi Monitor is a non-invasive continuous temperature monitor. Celsi Monitor achieves its intended purpose by measuring temperature at the surface of a neonate's abdomen by sensing changes in electrical resistance of a thermistor that is in thermal contact with the skin at the measured point. Celsi Monitor is provided with the Celsi Probe and Celsi Belt. The Celsi Monitor is powered by two rechargeable lithium-ion batteries. Both the Celsi Belt and Celsi Probe are reusable. The device displays measured patient body temperature for up to 12 hours and alarms when the temperature falls outside normothermic levels (<36.5 or >37.5 °C). The device is a skin contacting surface device with duration of contact < 24 hours.

INDICATIONS FOR USE

Celsi Monitor is intended for use in hospitals under a clinician's supervision or at their direction to assist nurses in continuous temperature monitoring of neonates. The device measures abdominal skin temperature through direct contact.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Hadleigh Health believes Celsi Monitor is substantially equivalent to the predicate device based on the information summarized here:

The subject device has a similar design and intended use as the device cleared in K083185. Both devices may be used on neonates, are intended to continuously monitor patient temperature, alert users if temperatures are outside of the normothermic range, and uses thermistors as temperature sensors. Both devices have temperature sensors that are applied directly to the skin on the abdomen. The main differences between the subject and predicate device are the temperature probe application and device display. The subject device uses an adjustable belt to maintain contact between the patient and the temperature probe (Celsi Probe). However, the temperature probe of the predicate device is adhered to the patient with a single use application tape. The temperature probe of the subject device connects to a small monitor (Celsi Monitor) with a screen to display results and alerts to the user. The predicate device's temperature probe wirelessly connects to a receiver which can then send temperature data and alerts to be displayed on a PC or tablet. However, these technological characteristics do not raise different questions of safety and effectiveness and have undergone testing to ensure the subject device is substantially equivalent to the predicate device.

In summary, the subject and predicate devices are based on the following same technological elements:

- Use of thermistor with direct skin contact on the abdomen

The following differences exist between the subject and predicate devices:

- Use of an adjustable belt to maintain contact between the patient and the temperature probe
- Use of a small monitor to display measurements

	Subject Device	*Predicate Device*	**Comparison**
	Hadleigh Health Technologies Celsi Monitor	CADI Scientific Pte.Ltd. Cadi SmartSense Wireless Temperature Monitoring System K083185	N/A
Indications for Use	Celsi Monitor is intended for use in hospitals under a clinician's supervision or at their direction to assist nurses in continuous temperature monitoring of neonates. The device measures abdominal skin temperature through direct contact.	The Cadi SmartSense Wireless Temperature Monitoring System is intended to measure abdominal surface temperature in adults through neonates. The ThermoSENSOR, a reusable temperature sensor, is applied to the patient by means of single use application tapes. The ThermoSENSOR provides periodic wireless transmission of temperature data which is utilized by the SmartNODE wireless receiver and the SmartSense PC application program to record, store, and display the temperature information. Warning: This equipment measures and reports abdominal surface temperature - where direct measurements of body core temperature are required, it is recommended to utilize appropriate core temperature monitoring devices for this purpose.	Similar: Both devices are intended to continuously monitor patient skin temperature, alert users to temperatures outside of the normothermic range, and use thermistors as temperature sensors. Temperature sensors are applied directly to the skin on the abdomen of neonates. Clinical and non-clinical testing have been adequately conducted to demonstrate the differences do not raise new or different questions of safety and effectiveness.
Product Codes / Regulation Number	FLL / 21 CFR 880.2910	FLL / 21 CFR 880.2910	Same
Regulation Name	Clinical Electronic Thermometer	Clinical Electronic Thermometer	Same
Monitoring Method	Thermistor-based temperature	Thermistor-based temperature sensor	Same

	sensor		
Temperature Measurement	Resolution: 0.1 °C Range: 25 to 43.9 °C	Unknown	Similar: Temperature measurements were evaluated by performance and clinical testing to demonstrate differences do not raise new or different questions of safety and effectiveness.
Contact Duration	12 hours	Unknown	Similar: Safety of contact duration evaluated by biocompatibility and clinical testing to demonstrate differences do not raise new or different questions of safety and effectiveness.
Patient Population	Neonates	Adults Pediatrics Neonates	Similar: The subject device has a patient population that is a subset of the predicate device. Both devices can be used on neonates.
Use Environment	Hospital environment	Hospital environment	Same
User	Healthcare professionals	Healthcare professionals	Same
Prescription Use	Yes	Yes	Same
Notifications/Alarms	Audio and visual alarms when temperature is <36.0 or >37.9 °C. Visual alarms when temperature is <36.5 or >37.5 °C	Unknown	Similar: Temperature measurement and alarms were evaluated by performance and clinical testing to demonstrate differences do not raise new or different questions of safety and effectiveness.
Power source	Rechargeable lithium-ion battery	Unknown	Similar: Safety and effectiveness of battery evaluated in accordance with IEC 62133.
Measurement site (skin/body)	Skin (abdomen)	Skin (abdomen)	Same
Mode (direct or adjusted)	Direct	Direct	Same
Mode (contact	Contact	Contact	Same

or non contact)			
Device Materials	Silicone, stainless steel, acrylonitrile butadiene styrene, and polyurethane	Unknown	Similar: Safety of materials evaluated by biocompatibility testing. Differences do not raise new or different questions of safety and effectiveness.
Shelf life/ In-use life	2 years	Unknown	Similar: Device use life evaluated by lifetime analysis testing. Differences do not raise new or different questions of safety and effectiveness.

SUMMARY OF NON-CLINICAL TESTING

Biocompatibility:

The subject device was evaluated for cytotoxicity, sensitization, and irritation in compliance to ISO 10993-5:2009, ISO 10993-10:2010, and ISO 10993-23:2010:2021.

Software Verification and Cybersecurity:

The software development and testing were executed with consideration to IEC 62304. Cybersecurity was evaluated per AAMI TIR57.

Electromagnetic Compatibility and Electrical Safety:

The subject device was tested in compliance with IEC 60601-1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2013, IEC 60601-1-8:2012, ISO 80601-2-56:2017, and IEC 62133:2012.

Performance testing:

Lifetime analysis testing after 100 simulated use cycles
ISO 80601-2-56:2017

SUMMARY OF CLINICAL TESTING

A short duration (3 hour) and long duration (12 hour) clinical evaluation was performed using the subject device to evaluate its temperature measurement accuracy and effects on the subject's skin. The subject device was compared to the reference device, the Philips Intellivue MP30 (K061610). Results from both studies demonstrated comparable temperature measurement accuracy between the subject and predicate devices.

CONCLUSION

Based on the performance testing, biocompatibility, software verification and validation, electromagnetic compatibility and electrical safety, and clinical testing, it can be concluded that the differences between the subject and predicate device do not raise new or different questions of safety and effectiveness. Therefore, the subject device, Celsi Monitor is substantially equivalent to the predicate device, Cadi SmartSense Wireless Temperature Monitoring System cleared under K083185.