Cooler Heads Care, Inc.
% Pierre Bounaud
Principal Consultant
Acknowledge Regulatory Strategies
2251 San Diego Avenue, Suite B-257
San Diego, California 92110

October 21, 2021

Re: K211526
Trade/Device Name: Portable Scalp Cooling System
Regulation Number: 21 CFR 878.4360
Regulation Name: Scalp Cooling System to reduce the likelihood of Chemotherapy-Induced Alopecia
Regulatory Class: Class II
Product Code: PMC
Dated: October 1, 2021
Received: October 4, 2021

Dear Pierre Bounaud:

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,

Neil R.P. Ogden
Assistant Director, THT4A4
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K211526

Device Name
Portable Scalp Cooling System

Indications for Use *(Describe)*
The Portable Scalp Cooling System (PSCS) is indicated to reduce the likelihood of chemotherapy-induced alopecia in cancer patients with solid tumors. The PSCS is indicated for adult patients only.

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.

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Cooler Heads

510(k) Summary

DATE PREPARED
May 13, 2021

MANUFACTURER AND 510(k) OWNER
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DEVICE INFORMATION

Proprietary Name/Trade Name:	Portable Scalp Cooling System (PSCS)
Common Name:	Scalp Cooling System
Regulation Number:	21 CFR 878.4360
Class:	II
Product Code:	PMC
Premarket Review:	OPEQ/OHT4/General Surgery Devices (DHT4A)
Review Panel:	General & Plastic Surgery

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

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K173032	Paxman Scalp Cooler / Paxman Coolers Ltd	✓

The predicate device has not been subject to a design related recall.

DEVICE DESCRIPTION
The Portable Scalp Cooling System (PSCS) is a wearable device for people undergoing chemotherapy treatment for solid tumor cancer who want to avoid chemotherapy-induced hair loss, or alopecia. Treatment with the PSCS is administered by a user or caregiver in a treatment center, during travel time to the patient's home and in the home setting. It is designed for continual use during the transition from the infusion center to the patient's home. The portable device provides the cooling therapy by circulating a water/isopropyl alcohol (IPA) mixture through a cooling cap worn securely on the patient’s head.

510(k) Summary

INDICATIONS FOR USE

The Portable Scalp Cooling System (PSCS) is indicated to reduce the likelihood of chemotherapy-induced alopecia in cancer patients with solid tumors. The PSCS is indicated for adult patients only.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Cooler Heads Care, Inc. believes that the PSCS is substantially equivalent to the predicate device based on the information summarized here:

The subject device has the same intended use as the device cleared in K173032. Both devices are scalp cooling systems intended to reduce the likelihood of chemotherapy-induced alopecia. The subject device is indicated for home use, while the predicate device is indicated for healthcare facilities. This difference has undergone human factor testing to ensure the device is as safe and effective as the predicate.

The subject device has similar, albeit more compact design, similar materials, and similar technological characteristics as the device cleared in K173032. The main technological differences of the subject device, as compared to the predicate device cleared in K173032, are:

- The type of coolant. The subject device uses a mixture of readily available 70% isopropyl alcohol, water, and ice. The predicate device uses a proprietary cooling mixture (OrbisC).
- The power source. The subject device was designed to be a mobile device and includes three different power sources: wall outlet (100-240 VAC – 50/60 Hz), internal rechargeable lithium battery, and a car charger (11-15 VDC 10A). The predicate device is intended to be plugged into a wall outlet only (100-120 VAC).

These technological differences have undergone testing to ensure the subject device is as safe and effective as the predicate device.

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the PSCS. The following tests were performed to demonstrate safety based on current industry standards:

- Electrical safety per IEC 60601-1, IEC 60601-1-6, and IEC 60601-1-11
- Electromagnetic compatibility per IEC 60601-1-2
- Software V&V per IEC 62304
- Performance bench testing (scalp cooling performance, cooling stability between power sources)
- Human factor testing per IEC 62366-1

The results of these tests indicate that the PSCS is substantially equivalent to the predicate device.

PSCS meets the requirements of ISO 10993-1 and FDA's *Guidance for Industry and Food and Drug Administration Staff - Use of International ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*, for a surface device with cumulative prolonged contact duration with intact skin.

CONCLUSION

Based on the testing performed, including electrical safety, electromagnetic compatibility, software V&V, performance bench testing, and human factor testing, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate device. The similar indications for use, technological characteristics, and performance characteristics for the proposed PSCS are assessed to be substantially equivalent to the predicate device.