DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 17, 2017

Paxman Coolers Limited
% Richard Vincins
Vice President, QA/RA
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K163484
Trade/Device Name: Paxman Scalp Cooler
Regulation Number: 21 CFR 878.4360
Regulation Name: Scalp Cooling System
Regulatory Class: Class II
Product Code: PMC
Dated: March 17, 2017
Received: March 21, 2017

Dear Richard Vincins:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163484

Device Name
Paxman Scalp Cooler

Indications for Use *(Describe)*
The Paxman Scalp Cooler is indicated to reduce the likelihood of chemotherapy-induced alopecia (CIA) in women with breast cancer.

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

Paxman Scalp Cooler

K163484

1. Submission Sponsor

Paxman Coolers Limited

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Huddersfield

HD8 0LE

United Kingdom

Contact: Richard PAXMAN

Title: Managing Director

2. Submission Correspondent

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Austin, TX 78746

Office Phone: (512) 327.9997

Contact: Carrie Hetrick, Senior Consultant, RA

Email: project.management@emergogroup.com

3. Date Prepared

17th March, 2017

4. Device Identification

Trade/Proprietary Name:	Paxman Scalp Cooler
Common/Usual Name:	Scalp Cooling System
Classification Name:	Scalp Cooling System to Reduce the Likelihood of Chemotherapy-Induced Alopecia
Regulation Number:	878.4360
Product Code:	PMC, Scalp Cooling System
Device Class:	Class II
Classification Panel:	General and Plastic Surgery

5. Legally Marketed Predicate Device

DEN150010, DigniCap™ Scalp Cooling System, Dignitana AB

6. Device Description

The Paxman Scalp Cooler is a self-contained, mobile, electrically-powered refrigeration unit that circulates a refrigerated liquid coolant, at a pre-set temperature and flow rate, through a cooling cap, which is fitted to the top of the patient's head and connected to the refrigeration unit by a pair of coolant lines. A touch screen controller with a menu-driven, graphical user interface, integrated into the refrigeration unit, allows the healthcare professional to initiate, monitor, and complete the scalp cooling process.

Two (2) models of the Paxman Scalp Cooler are available:

- ORBIS I – featuring one pair of coolant lines for attaching a single cooling cap; designed for scalp cooling of one patient at a time; and,
- ORBIS II – featuring two pairs of coolant lines for attaching two cooling caps; designed for scalp cooling of up to two (2) patients at a time.

The touch screen displays a menu-driven Graphical User Interface (GUI) that provides information to the user concerning the operational status of the scalp cooling unit; it also prompts the user to initiate certain actions relating to the scalp cooling procedure and provides a timer count-down function for scalp cooling sessions. The GUI does not, however, directly control the scalp cooling process as there are pre-established programs for the scalp cooling administration.

The touch screen controller provides feedback to the user concerning the status of the Paxman Scalp Cooler as it relates to achievement of the pre-set temperature of the coolant, operation of the recirculation pump and connection of a cooling cap to the system. The software also provides a timer count-down function for the initiated pre- and post-infusion cooling procedure. At the end of the pre-

set time, a message is displayed on the touch screen and a buzzer sounds to alert the user to the fact that the scalp cooling time is complete.

7. Indication for Use Statement

The Paxman Scalp Cooler is indicated to reduce the likelihood of chemotherapy-induced alopecia (CIA) in women with breast cancer.

8. Substantial Equivalence Discussion

The following table compares the Paxman Scalp Cooler to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5A – Comparison of Characteristics

Manufacturer	**Paxman Coolers Limited**	**Dignitana AB**	**Significant Differences**
Trade Name	**Paxman Scalp Cooler**	**DigniCap™ Scalp Cooling System**	
510(k) Number	Not assigned	DEN150010	Not applicable
Product Code	PMC	PMC	Same
Regulation Number	878.4360	878.4360	Same
Regulation Name	Scalp Cooling System	Scalp Cooling System	Same
Indications for Use	The Paxman Scalp Cooler is indicated to reduce the likelihood of chemotherapy-induced alopecia (CIA) in women with breast cancer.	The DigniCap™ Scalp Cooling System is indicated to reduce the likelihood of chemotherapy - induced alopecia in women with breast cancer.	Same
Mechanism of Action	The unit is a compact, mobile refrigeration unit which circulates liquid coolant at low pressure through a special cooling cap on the patient's head. The circulation of the refrigerated coolant	The Dignitana DigniCap™ Scalp Cooling System consists of a computer controlled system that includes a refrigerated tank containing the cooling agent. The liquid coolant circulates from the cooling unit to and	Same

Manufacturer	**Paxman Coolers Limited**	**Dignitana AB**	**Significant Differences**
Trade Name	**Paxman Scalp Cooler**	**DigniCap™ Scalp Cooling System**	
	through the cap extracts heat from the patient's scalp maintaining temperature.	through the channels of the cap and back to the cooling unit. The circulation of the refrigerant extracts heat from the patient's scalp maintaining a temperature.	
Technology Overview	The unit is composed of a main unit that contains the refrigeration components, touch screen controller, and coolant tank. There are detachable coolant lines with covers, detachable cooling cap with covers, and proprietary coolant.	The DigniCap Cooling System consists of a refrigerator unit with integral control system operated via a touch screen monitor and capable of controlling two separate cooling caps. The scalp cooling is performed in conjunction with a silicone inner cap, outer neoprene cap, and the liquid coolant which are proprietary.	Same
Patient Population	Women with Stage I – II breast cancer undergoing neoadjuvant or adjavent chemotherapy.	Women with Stage I – II breast cancer undergoing neoadjuvant or adjavent chemotherapy.	Same
Set Cooling Time	Yes	Yes	Same
Pre/Post Cooling Time	Yes	Yes	Same
Material of Cooling Cap	Silicone	Silicone	Same
Size of Cooling Cap	Small, Medium, Large	Extra Small, Small, Medium, and Large	Similar; there is an additional Extra Small cooling cap provided for predicate does not

Manufacturer	**Paxman Coolers Limited**	**Dignitana AB**	**Significant Differences**
Trade Name	**Paxman Scalp Cooler**	**DigniCap™ Scalp Cooling System**	
			raise any additional concerns for safety or efficacy.
Number of Cooling Caps/Lines	2	2	Same
Quick Disconnect	Yes	Yes	Same
Coolant Temperature Range	-15°C to 5°C	-15°C to 5°C	Same
Refrigerant Type	Proprietary coolant	Proprietary coolant	Similar; both are refrigerants that are used for cooling purposes. Performance testing of the system does not raise any additional questions for safety and efficacy.
Coolant Refilling	Yes	Yes	Same
Sterile	No	No	Same
Single-Use	No	No	Same
Touch Screen Interface	Yes	Yes	Same
Software Controlled	Yes	Yes	Same
Complies with ISO 10993-1	Yes	Yes	Same
Electrical Safety Testing Passed	Yes	Yes	Same

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of Paxman Scalp Cooler and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, Paxman Coolers Limited completed a number of non-clinical performance tests. The Paxman Scalp Cooler meets all the

requirements for overall design, labeling, biocompatibility, software testing, and electrical safety results confirming that the design output meets the design inputs and specifications for the device.

The Paxman Scalp Cooler passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Biocompatibility testing of Cooling Cap per ISO 10993-1: ***Passed***
- Electrical safety testing per ANSI/AAMI ES60601-1: ***Passed***
- Electromagnetic Disturbance (EMD) testing per IEC 60601-1-2: ***Passed***
- Software verification and validation testing per IEC 62304/FDA Guidance
- Useable life of the device of five (5) years and Cooling Cap shelf life of three (3) years
- Storage and Transport Testing conformance to ISTA requirements: ***Passed***
- Heat extraction validation testing
- Scalp temperature validation testing
- Performance testing of coolant management: ***Passed***
- Leak testing of Cooling Cap: ***Passed***

10. Clinical Performance Data

A clinical study was conducted to evaluate safety and efficacy of the Paxman Scalp Cooler to physically cool the scalp of patients who are undergoing chemotherapy for the treatment of breast cancer, in order to reduce chemotherapy-induced alopecia. The study was a prospective, randomized, two-arm study of women with Type I-II breast cancer undergoing chemotherapy treatment with Paxman Scalp Cooler used as the cooling arm and no cooling serving as the control group. The overall summary of the clinical study is shown:

- Study Design: The study was a prospective, randomized, two-arm study of women with breast cancer undergoing chemotherapy to evaluate effect of scalp cooling to reduce chemotherapy-induced alopecia.
- Study Objectives: To demonstrate that the Paxman Scalp Cooler is safe and effective in reducing chemotherapy-induced alopecia in women with breast cancer undergoing neoadjuvant or adjuvant chemotherapy
    - Comparing success in hair preservation, between the Paxman Scalp Cooler (cooling arm) and control group (no cooling arm) after four (4) cycles of chemotherapy
    - To estimate the rate of significant cold-related anticipated adverse device effects (AADEs) self-reported by subjects during treatment with the Paxman Scalp Cooler

- Study Endpoints: All eligible study subjects who receive at least one (1) cycle of chemotherapy will be evaluable for hair-preservation response: success in hair preservation by a Healthcare Professional, success in hair preservation by subject self and Oncologist, use of wigs and/or hair wrap, and Quality of Life using three questionnaires.

- Study Procedure: All subjects are randomized to cooling arm will undergo scalp cooling using the Paxman Scalp Cooler, during and after administration of each chemotherapy session, for four (4) complete cycles of full-dose anthracycline or taxane based chemotherapy that are specified in inclusion criteria for the chemotherapy treatment regimen.

  Scalp cooling will begin a minimum of 30 minutes pre-infusion administration of chemotherapy. Cooling commences for the duration of chemotherapy treatment administered by the Paxman Scalp Cooler. Temperature will be maintained through scalp cooling with the device a minimum of 90 minutes post-infusion.

  At baseline and after each cycle, subjects will have an alopecia assessment by a delegated physician or nurse practitioner and a second independent healthcare provider who is blinded to study treatment. Each subject will be followed up 2-3 weeks after completion of each chemotherapy cycle, and 2-4 weeks after completion of the final chemotherapy cycle.

- Number of Patients/Sites: Number of evaluable subject is 142 (one hundred forty two) that were analyzed based on the intent to treat (ITT) population across six (6) clinical sites in the United States.

- Study Treatment: Duration of device use depends on the type of chemotherapy the subject is receiving; subject is assessed after each cycle of chemotherapy (maximum of 8 cycles).

- Results Effectiveness: Of the 142 evaluable patients, 95 were in the cooling group and 47 were in the control group (no cooling). Results show 48 (50.5%) out of 95 in the cooling group and 0 (0%) out of 47 in the control group had hair preservation. The success rate difference between the two groups was 50.5%, 95% CI: 40.5% - 60.6%, one-tailed p-value from the Fisher's exact test was <0.0001.

- Results Safety: Total of 28 patients (27.7%) had 54 adverse events in combination through all treatment sessions. All adverse events were grade 1 or 2. There was no serious adverse device event.

Results of the clinical investigation support the safety, efficacy, and indications for use of the Paxman Scalp Cooler in reducing chemotherapy-induced alopecia by achieving less than 50% hair loss compared with no scalp cooling after chemotherapy treatment. Clinical study conclusion confirms that the device is safe and effective as used according to the instructions for use.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Based on the comparison and analysis above, the Paxman Scalp Cooler is determined to be substantially

equivalent to the referenced predicate device.