Dignitana Inc.
℅ Valerie Defiesta-Ng
Vice President, Regulatory Affairs
Experien Group
224 Airport Parkway, Suite 250
San Jose, California 95110

June 26, 2019

Re: K191166
Trade/Device Name: DigniCap Delta
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: April 30, 2019
Received: May 1, 2019

Dear Valerie Defiesta-Ng:

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, MS
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: 0MB No. 0910-0120
Expiration Date: 06/30/2020
See *PRA Statement below.*

510(k) Number *(if known)*

K191166

Device Name
DigniCap Delta® Scalp Cooling System

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

Type of Use *(Select one or both, as applicable)*

XX 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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510(k) Notification K191166

GENERAL INFORMATION

Applicant:

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Phone: 469-917-5555
info@dignitana.com

Contact Person:

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Vice President, Regulatory Affairs
Experien Group, LLC
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San Jose, CA 95110
USA

Date Prepared: April 30, 2019

DEVICE INFORMATION

Trade/Proprietary Name:
DigniCap Delta®

Generic/Common Name:
Scalp Cooling System

Classification:
21 CFR §878.4360

Product Code:
PMC

Establishment Registration:
3012146457– Dignitana, Inc. Dallas, Texas 2019, Complaint File Establishment

Manufacturing Facility:
Dignitana, Inc.
10925 Estate Lane, Suite W-185
Dallas, Texas 75238

PREDICATE DEVICE(S)

DigniCap Delta is substantially equivalent to the predicate device, the Dignitana DigniCap Scalp Cooling System, cleared under K170871. DigniCap Delta is intended for use in the same population, with the same mechanism of action and Indications for Use. Any differences in the technological characteristics between the devices do not raise different questions of safety or effectiveness.

DEVICE DESCRIPTION

The DigniCap Delta Scalp Cooling System ("DigniCap Delta")is a device that is intended to function as a cooling system to reduce the likelihood of chemotherapy-induced alopecia in cancer patients with solid tumors. The proposed therapy of the new device is comparable to the therapy of the predicate device, DigniCap Scalp Cooling System (K170871).

DigniCap Delta cools fluid to a prescribed set temperature and circulates that cooled fluid through a cooling wrap and then back to the device. This mode of operation is equivalent to other scalp cooling devices. User operation of the DigniCap Delta system is carried out on the illuminated graphics display with the integrated touch control, located on the front of the unit. The navigation and selection buttons on the display are used to interface with the device.

INDICATIONS FOR USE

The DigniCap Delta® Scalp Cooling System is indicated to reduce the likelihood of chemotherapy-induced alopecia in cancer patients with solid tumors.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

DigniCap Delta is substantially equivalent to the predicate device, the Dignitana DigniCap® Scalp Cooling System, cleared under K170871. Any differences in the technological characteristics between the devices do not raise different questions of safety or effectiveness. DigniCap Delta has the same Indications for Use, population and mechanism of action as the predicate device. Thus, DigniCap Delta is substantially equivalent to the predicate device.

The tables below compare the regulatory information (Table 5.1) and technical characteristics (Table 5.2) for the proposed and predicate devices.

Table 5.1: Substantial Equivalence Table – Regulatory Information

Feature	DigniCap Delta® Scalp Cooling System (Subject Device)	DigniCap® Scalp Cooling System (Predicate Device)	Analysis of Differences
510(k) Number	To Be Assigned	K170871	N/A
Classification	II	II	Same
Product Code	PMC	PMC	Same
Regulatory Number	§878.4360	§878.4360	Same
Regulation Name	Scalp Cooling System	Scalp Cooling System	Same
Indications for Use	The DigniCap Delta® Scalp Cooling System is indicated to reduce the likelihood of chemotherapy-induced alopecia in cancer patients with solid tumors.	The DigniCap® Scalp Cooling System is indicated to reduce the likelihood of chemotherapy-induced alopecia in cancer patients with solid tumors.	Same
Mechanism of Action	The DigniCap Delta Scalp Cooling System transports temperature controlled cooled fluid from the device to a cooling cap to cool the patient's scalp thus reducing chemotherapy-induced alopecia	The DigniCap Scalp Cooling System transports temperature controlled cooled fluid from the device to a cooling cap to cool the patient's scalp thus reducing chemotherapy-induced alopecia.	Same
Population	Chemotherapy Patients with Solid Tumors	Chemotherapy Patients with Solid Tumors	Same

Table 5.2: Substantial Equivalence Table – Technological Information

Feature	DigniCap Delta® Scalp Cooling System (Subject Device)	DigniCap® Scalp Cooling System (Predicate Device)	Analysis of Differences
Technological Features	The DigniCap Delta Scalp Cooling System consists of a solid-state thermoelectric cooling unit with integral control system operated via a touchscreen monitor, capable of precisely controlling the temperature of one cooling cap.	The DigniCap Scalp 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.	Any differences in the technological characteristics between the devices do not raise different questions of safety or effectiveness.
User Interface	Touchscreen	Touchscreen	Same Updated for user ease.
Cooling Cap Features			
Inner Cooling Cap	Yes, includes adjustable tabs	Yes	The differences in the technological characteristics between the devices are minor and do not raise different questions of safety or effectiveness.
Detachable Coolant Lines	Yes	Yes	Same
Outer Cover/ Material	Yes/Neoprene	Yes/Neoprene	Same
Cooling Fluid Required	Yes	Yes	Cooling fluid is similar; the DigniCap Delta uses an isopropyl alcohol/water mixture, while the predicate uses MPG (monopropylene glycol). The cooling fluids are used for the same purpose. This difference does not raise different questions of safety or effectiveness as demonstrated by performance testing.
Fluid Temperature	Fluid temperatures are regulated through temperature sensors in the fluid lines.	Fluid temperatures are regulated through temperature sensors in the cooling cap.	The sensors are located in a different region but are used for the same purpose and have been tested to prove that they work as effectively as the predicate device. This difference does not raise different questions of safety or effectiveness as demonstrated by performance testing.

Table 5.2: Substantial Equivalence Table – Technological Information (cont.)

Feature	DigniCap Delta® Scalp Cooling System (Subject Device)	DigniCap® Scalp Cooling System (Predicate Device)	Analysis of Differences
Pre /Post Cooling Phase	Yes	Yes	Same
Coolant Temperature Range	-7 to 1.5°C	-15°C to 5°C	This range is within the range originally cleared with the predicate device but is tighter to provide more consistent cooling to the patient's scalp. This difference does not raise different questions of safety or effectiveness.
Outer Cooling Cap	Single Patient Use	Multiple Patient Use	This difference does not raise different questions of safety or effectiveness.
Inner Cooling Cap – Single Use	Single Patient Use	Multiple Patient Use	This difference does not raise different questions of safety or effectiveness.
Device Testing			
Biocompatibility Testing	Yes. Cap materials are biocompatible in accordance with ISO 10993-1.	Yes. Cap materials are biocompatible in accordance with ISO 10993-1.	Same
Electrical Safety Testing	Yes. IEC 60601-1:2005/(R)2012 IEC 62133-2:2017	Yes. IEC 60601-1:2007	Electrical Safety Testing was conducted to the current standard.
Electromagnetic Compatibility Testing	Yes. IEC60601-1-2:2014	Yes. IEC 60601-1-2:2007	Electrical Safety Testing was conducted to the current standard.

SUBSTANTIAL EQUIVALENCE

DigniCap Delta has the same Indications for Use, patient population and mechanism of action as the predicate device (K170871). Any differences in the technological characteristics between the devices do not raise different questions of safety or effectiveness. Thus, DigniCap Delta is substantially equivalent to the predicate device.

PERFORMANCE DATA

All necessary non-clinical performance testing was conducted on DigniCap Delta to support a determination of substantial equivalence to the predicate device.

Nonclinical Testing Summary:

DigniCap Delta was tested to confirm the device met all performance requirements and is considered safe and effective for its intended use. Testing was completed per relevant FDA guidance documents. Specifically, the device was evaluated for the following through nonclinical, bench testing:

- Biocompatibility Testing of Cooling Cap (Cap materials are biocompatible in accordance with ISO 10993-1)
- Accessory Performance Testing
- Stable Fluid Temperature Verification
- Notifications and Alarms System Testing
- Electrical Safety in accordance with IEC 60601-1:2005(R)2012 and IEC 62133-2:2017 and Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2014
- Software verification and validation testing

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of DigniCap Delta meet the established specifications necessary for consistent performance during its intended use. The bench testing has demonstrated that the DigniCap Delta can maintain and adjust cooling fluid temperature as needed to meet the predetermined treatment specifications. The collective bench testing demonstrates that DigniCap Delta does not raise new questions of safety or effectiveness for scalp cooling when compared to the predicate devices.

Clinical Testing Summary:

Not applicable. Clinical testing was not performed to support this 510(k) submission.

CONCLUSIONS

The collective results of the performance testing demonstrate that DigniCap Delta meets the established specifications necessary for consistent performance during its intended use. In addition, the collective performance testing demonstrate that DigniCap Delta does not raise different questions of safety or effectiveness when compared to the predicate device.

Based on the non-clinical performance testing results, the differences in the technological characteristics between the subject and predicate devices do not raise any new issues of safety or

effectiveness. DigniCap Delta is intended for use in the same population and with the same Indications for Use as its predicate device. Thus, DigniCap Delta is substantially equivalent to the predicate device.