DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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December 8, 2015

Dignitana AB
c/o Glen D. Park, PharmD
Target Health, Inc.
261 Madison Avenue, 24th Floor
New York, New York 10016

Re: DEN150010
DigniCap™ Scalp Cooling System
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 878.4360
Regulation Name: Scalp Cooling System to Reduce the Likelihood of Chemotherapy-Induced Alopecia
Regulatory Classification: Class II
Product Code: PMC
Dated: March 6, 2015
Received: March 6, 2015

Dear Dr. Park:

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 DigniCap™ Scalp Cooling System, a prescription device under 21 CFR Part 801.109 that is indicated to reduce the likelihood of chemotherapy-induced alopecia in women with breast cancer. FDA concludes that this device should be classified into class II. This order, therefore, classifies the DigniCap™ Scalp Cooling System, and substantially equivalent devices of this generic type, into class II under the generic name, Scalp cooling system to reduce the likelihood of chemotherapy-induced alopecia.

FDA identifies this generic type of device as:

> **Scalp cooling system to reduce the likelihood of chemotherapy-induced alopecia.** A scalp cooling system to reduce the likelihood of chemotherapy-induced alopecia is a prescription device intended to reduce the frequency and severity of alopecia during chemotherapy in which alopecia-inducing chemotherapeutic agents are used.

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 new 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, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. 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** classifying the device type.

On March 6, 2015, FDA received your *de novo* requesting classification of the DigniCap™ Scalp Cooling System into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify DigniCap™ Scalp Cooling 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 the DigniCap™ Scalp Cooling System indicated to reduce the likelihood of chemotherapy-induced alopecia in women with breast cancer 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 and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	**Mitigation Measure**
Thermal Tissue Damage	Non-clinical Performance Testing Software Verification, Validation, and Hazard Analysis Labeling
Electromagnetic Interference / Electrical Shock	Electromagnetic Compatibility and Electrical Testing Labeling
Adverse Tissue Reaction	Biocompatibility
Increased Risk of Scalp Metastases	Labeling Patient Labeling
Use Error	Labeling
Scalp Pain, Headache, and Chills	Labeling Patient Labeling

In combination with the general controls of the FD&C Act, the Scalp Cooling System to Reduce the Likelihood of Chemotherapy-Induced Alopecia is subject to the following special controls:

1. Non-clinical performance testing must demonstrate that the device meets all design specifications and performance requirements, and that the device performs as intended under anticipated conditions of use. This information must include testing to demonstrate accuracy of the temperature control mechanism.

2. Performance testing must demonstrate the electromagnetic compatibility (EMC) and electrical safety of the device.

3. Software verification, validation, and hazard analysis must be performed.

4. The patient contacting components of the device must be demonstrated to be biocompatible. Material names must be provided.

5. Labeling must include the following:

    a) A statement describing the potential risk of developing scalp metastasis.

    b) Information on the patient population and chemotherapeutic agents/regimen for which the device has been demonstrated to be effective.

    c) A summary of the non-clinical and/or clinical testing pertinent to use of the device.

    d) A summary of the device technical parameters, including temperature cooling range and duration of cooling.

    e) A summary of the device- and procedure-related adverse events pertinent to use of the device.

    f) Information on how the device operates and the typical course of treatment.

6. Patient labeling must be provided and must include:

    a) Relevant contraindications, warnings, precautions, adverse effects/complications.

    b) Information on how the device operates and the typical course of treatment.

    c) Information on the patient population for which there is clinical evidence of effectiveness.

    d) The potential risks and benefits associated with use of the device.

    e) Post-operative care instructions.

    f) A statement describing the potential risk of developing scalp metastasis.

In addition, this is a prescription device and must comply with 21 CFR 801.109. 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 Scalp cooling system to reduce or prevent the likelihood of chemotherapy induced alopecia they intend to market prior to marketing the device and receive clearance to market from FDA.

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); 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 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.

If you have any questions concerning this classification order, please contact Mr. Richard Felten at 301-796-6392.

Sincerely yours,

Jonette R. Foy -S

Jonette Foy, Ph.D.
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