



Food and Drug Administration
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May 13, 2016

Cerêve, Inc.
% Miriam C. Provost, Ph.D.
Biologics Consulting Group, Inc.
400 North Washington Street, Suite 100
Alexandria, Virginia 22314

Re: DEN140032
Cerêve Sleep System
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 882.5700
Regulation Name: Thermal System for Insomnia
Regulatory Classification: Class II
Product Code: PLU
Dated: October 17, 2014
Received: October 20, 2014

Dear Dr. Provost:

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 Cerêve Sleep System, a prescription device under 21 CFR Part 801.109 that is indicated *to reduce sleep latency to Stage 1 and Stage 2 sleep in patients with primary insomnia*. FDA concludes that this device should be classified into class II. This order, therefore, classifies the Cerêve Sleep System, and substantially equivalent devices of this generic type, into class II under the generic name, thermal system for insomnia.

FDA identifies this generic type of device as:

Thermal System for Insomnia: A thermal system for insomnia is a prescription device for use in patients with insomnia that is used to apply a specified temperature to the skin surface.

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 October 20, 2014, FDA received your *de novo* requesting classification of the Cerève Sleep System into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Cerève Sleep 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 Cerève Sleep System indicated *to reduce sleep latency to Stage 1 and Stage 2 sleep in patients with primary insomnia* can be classified in class II with the establishment of special controls. 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
Adverse Skin Reaction	Biocompatibility Assessment Labeling
Electromagnetic Interference with Other Devices	Electromagnetic Compatibility Testing Labeling
Electrical Safety (e.g., shock)	Electrical Safety Testing Labeling
Thermal Injury	Non-clinical Performance Testing Software Verification, Validation, and Hazard Analysis Labeling

In combination with the general controls of the FD&C Act, the Thermal System for Insomnia is subject to the following special controls:

1. The patient-contacting components of the device must be demonstrated to be biocompatible.
2. Performance testing must demonstrate electromagnetic compatibility and electrical safety.
3. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be evaluated:
 - a. Thermal performance of the device, including maintenance of the target temperature, must be evaluated under simulated use conditions.
 - b. Mechanical testing to demonstrate the device can withstand forces under anticipated use conditions.
 - c. Mechanical testing to demonstrate the device is resistant to leakage under anticipated use conditions.
4. Software verification, validation, and hazard analysis must be performed.

5. Patient labeling must be provided to convey information regarding safe use of the device, including instructions for assembly.

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 Thermal System for Insomnia 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 Leigh Anderson at 301-796-6610.

Sincerely,

Jonette Foy, Ph.D.
Deputy Director
for Engineering and Science Review
Office of Device Evaluation
Center for Devices and
Radiological Health