DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 2004

David L. Bremseth, Pharm.D
Vice President, Clinical and Regulatory Affairs
Celleration, Inc.
6570 Edenvale Boulevard
Eden Prairie, Minnesota 55346

Re: K032378
Evaluation of Automatic Class III Designation
Celleration MIST Therapy System™
Regulation Number: 21 CFR 878.4410
Classification: Class II
Product Code: NRB

Dear Dr. Bremseth:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for classification of the Celleration MIST Therapy System™ that is intended for the cleaning and maintenance debridement of wounds. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Celleration Mist Therapy System™, and substantially equivalent devices of this generic type into class II under the generic name, Low Energy Ultrasound Wound Cleaner. This order also identifies the special controls applicable to this device, entitled, "Class II Special Controls Guidance Document: Low Energy Ultrasound Wound Cleaner.

FDA identifies this generic type of device as:

21 CFR 878.4410 Low Energy Ultrasound Wound Cleaner

A low energy ultrasound wound cleaner is a device that uses ultrasound energy to vaporize a solution and generate a mist that is used for the cleaning and maintenance debridement of wounds. Low levels of ultrasound energy may be carried to the wound by the saline mist.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as post-amendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues

an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, with in 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 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.

On April 29, 2004, FDA filed your petition requesting classification of the Celleration MIST Therapy System™ into class II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA issued an order on April 8, 2004, automatically classifying the Celleration MIST Therapy System™ in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, which was subsequently reclassified into class I or class II. In order to classify the Celleration MIST Therapy 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 petition, FDA has determined that the Celleration MIST Therapy System™ intended for the cleaning and maintenance debridement of wounds 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.

The potential risks to health associated with the device are: delayed wound healing, thermal damage, inflammation/foreign body response, infection and electrical shock. The special controls document aids in mitigating the risk by establishing performance characteristics, safety testing, and appropriate labeling.

In addition to the general controls of the act, the low energy ultrasound wound cleaner is subject to the following special controls: Class II Special Controls Guidance Document: Low Energy Ultrasound Wound Cleaner.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Thus, persons who intend to market this device

must submit to FDA a premarket notification submission containing information on the device they intend to market prior to marketing the device.

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 this device, subject to the general control provisions of the Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact David B. Berkowitz, Ph.D., V.M.D., at 301 594-3090, extension 152.

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Office of Device Evaluation
Center for Devices and Radiological Health