DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 29 1998

Mr. Timothy R. Littlefield
Director, Research and Development
Cranial Technologies, Inc.
1331 North 7th Street, Suite 170
Phoenix, Arizona 85006

Re: Evaluation of Automatic Class III Designation - Dynamic Orthotic Cranioplasty - DOC™ Band - K964992
Dated: Undated
Received: March 31, 1998

Dear Mr. Littlefield,

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition, submitted in accordance with section 513(f)(2) of the Food, Drug, and Cosmetic Act, for classification of the Dynamic Orthotic Cranioplasty - DOC™ Band that is intended for use on infants from three to eighteen months of age with moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads. The device is intended to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Dynamic Orthotic Cranioplasty - DOC™ Band, and substantially equivalent devices of this generic type into class II under the generic name, cranial orthosis. This order also identifies the special controls applicable to this device.

FDA identifies this generic type of device as a neurology device under 21 CFR 882.5970, as a cranial orthosis which is a device intended for medical purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape. It is used to treat infants from three to eighteen months of age, with moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

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 postamendments 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, within 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.

In accordance with section 513(f)(1) of the act, FDA issued an order on March 12, 1998, automatically classifying the Dynamic Orthotic Cranioplasty - DOC™ Band 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. On March 31, 1998, FDA filed your petition requesting classification of the Dynamic Orthotic Cranioplasty - DOC™ Band into class II. The petition was submitted under section 513(f)(2) of the act. In order to classify the Dynamic Orthotic Cranioplasty - DOC™ Band 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 and in the medical literature, FDA has determined that the Dynamic Orthotic Cranioplasty - DOC™ Band, intended for use in infants from three to eighteen months of age with moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads, to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape, 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.

FDA has identified the following risks to health associated with this type of device: (a) skin irritation, skin breakdown and subsequent infection due to excessive pressure on the skin; (b) head and neck trauma due to alteration of the functional center of mass of the head and the additional weight of the device especially with an infant who is still developing the ability to control his/her head and neck movements; (c) impairment of brain growth and development from mechanical restriction of cranial growth; (d) asphyxiation due to mechanical failure, poor

fit, and/or excessive weight that alters the infant's ability to lift the head; (e) eye trauma due to mechanical failure, poor construction and/or inappropriate fit; (f) contact dermatitis due to the materials used in the construction of the device.

In addition to the general controls of the act, the Dynamic Orthotic Cranioplasty - DOC™ Band is subject to the following special controls in order to provide reasonable assurance of the safety and effectiveness: (1) The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109. (2) The labeling must include (a) contraindications for the use of the device on infants with synostosis or with hydrocephalus; (b) warnings indicating the need: (i) to evaluate head circumference measurements and neurological status at intervals appropriate to the infant's age and rate of head growth, and to describe steps that should be taken in order to reduce the potential for restriction of cranial growth and possible impairment of brain growth and development; (ii) to evaluate the skin at frequent intervals, e.g., every three to four hours, and to describe steps that should be taken if skin irritation or breakdown occurs; (c) precautions indicating the need: (i) to additionally treat torticollis, if the positional plagiocephaly is associated with torticollis; (ii) to evaluate device fit and to describe the steps that should be taken in order to reduce the potential for restriction of cranial growth, possible impairment of brain growth and development and skin irritation and/or breakdown; (iii) to evaluate the structural integrity of the device and to describe the steps that should be taken to reduce the potential for the device to slip out of place and cause asphyxiation or trauma to the eyes or skin; (d) adverse events, i.e., skin irritation and breakdown that have occurred with the use of this device; (e) clinician's instructions for casting the infant, for fitting the device, and for care and use of the device; and (f) parents' instructions for care and use of the device. (3) The materials must be assessed for biocompatibility with testing appropriate for long term direct skin contact.

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 and, therefore, the device is not exempt from the premarket notification requirements. Thus, persons who intend to market this device must submit to FDA a premarket notification 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, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

FDA also requests that you submit final labeling to us as soon as possible and before commercial distribution of your device. If you have any questions concerning this classification order, please contact Mr. James Dillard, Deputy Director, Division of General and Restorative Devices, at (301) 594-1184.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health