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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

C. Michael Schuch, CPO, FISPO, FAAOP
President
American Orthotic & Prosthetic Association
1650 King Street, Suite 500
Alexandria, Virginia 22314

Re: Cranial Helmet Citizen Petition
Dated: March 3, 2000
Received: March 13, 2000
Docket No. 00P-1085

Dear Mr. Schuch:

The Food and Drug Administration (FDA) has received your Citizen Petition requesting the classification of the cranial helmet. The cranial helmet is an orthotic device used to provide protection for patients' skulls following cranial surgery and for skull protection in general. You request that the cranial helmet be classified as a Class I device exempt from the premarket notification requirements.

The cranial helmet you describe is indicated to protect the cranium of patients who have undergone extensive cranial surgery or who are subject to spastic or uncontrollable movements due to certain diseases (e.g., cerebral palsy). You describe the helmet as "basically a specialized wound bandage." The petition states that the preamendments indication for use is "[p]rotection of the cranium (skull). A common use for this helmet is to protect the skull after surgery to reverse or ameliorate premature synostosis in infants. If uncorrected, this results in a badly deformed skull for the child. The helmet can also be used at the discretion of the physician to protect the skull after any type of cranial surgery and for skull protection in patients suffering from uncontrollable movement as sometimes observed with cerebral palsy."

When intended solely for protection, the FDA agrees that the cranial helmet is a Class I device under 21 CFR 890.3025, Prosthetic and Orthotic Accessory. A prosthetic and orthotic accessory is a device intended for medical purposes to support, protect, or aid in the use of a cast, orthosis (brace), or prosthesis. The device is exempt from the premarket notification procedures in subpart E of part 807, subject to the Limitations of Exemptions found in 21 CFR 890.9 (copy enclosed). The device also is exempt from the current good manufacturing practice regulations in part 820, with the exception of section 820.180, with respect to general requirements concerning records, and section 820.198, with respect to complaint files.

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On May 29, 1998, the FDA classified the 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. Under 21 CFR 882.5970, these are Class II devices 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. The FDA believes that the cranial helmet is of the type of device included in the cranial orthosis classification when intended for improvement in cranial symmetry and or shape. Therefore, while cranial helmets intended solely for protection may be Class I exempt, cranial helmets intended to improve cranial symmetry and/or shape will require premarket notification under Part 807 – Subpart E, prior to marketing in the United States.

If you have any questions please contact Russ Pagano, at (301) 594-1296, ext. 159.

Sincerely,

A handwritten signature in black ink that reads "Linda S. Kahan". The signature is written in a cursive style with a large initial "L".

Linda S. Kahan
Deputy Director for Regulations
and Policy
Center for Devices and
Radiological Health

Enclosure