SPORTS/MED EQUIPMENT

DANMAR PRODUCTS, INC.
221 JACKSON INDUSTRIAL DRIVE • ANN ARBOR, MI. 48103 • USA

K013452

OCT 31 2003

510(k) SUMMARY

Danmar Products, Inc.
Cranial Adjustive Prosthesis

October 17, 2001

Submitter Information:

Danmar Products, Inc.
221 Jackson Industrial Drive
Ann Arbor, MI 48103

Submitter's Name:	Karen A. Lindner
Phone:	734-761-1990

Device Narne:

Proprietary Name:	Cranial Adjustive Prosthesis
Common Name:	Cranial Band or Helmet
Classification Name:	Cranial Orthosis

Predicate Device Equivalence:

Substantial equivalence is claimed to the Cranial Technologies Dynamic Orthotic Cranioplasty--DOC Band, cleared for commercial distribution through the approved evaluation of an automatic Class III designation, and to the Michigan Cranial Helmet cleared for commercial distribution per K003630.

(800) 783-1998
(734) 761-1990
Fax
(734) 761-8977
e-mail:
danmarpro@aol.com
Internet:
http://www.
danmarproducts.com

Device Description:

The Danmar Products Cranial Adjustive Prosthesis is constructed with front and rear sections that are comprised of an inner, soft foam that is ⅛" to ¼" thick, and an outer shell made of a semi-rigid plastic.

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Intended Use:

The Danmar Products Cranial Adjustive Prosthesis is intended for prescription use to be used to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry andlor shape in infants from 3 to 14 months of age, with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic- and brachycephalic-shaped heads.

Comparison of Technological Characteristics:

The Danmar Products Cranial Adjustive Prosthesis has the same technological characteristics as the predicate devices.

Summary of Device Evaluation:

The literature on this and similar devices demonstrates that the Danmar Products Cranial Adjustive Prosthesis performs as intended. Biocompatibility data demonstrates that the device's inner lining is nonirritating and nontoxic. Test data demonstrates that the device will not break or shatter when subjected to impact.

Conclusions:

Based on the above, we concluded that the Danmar Products Cranial Adjustive Prosthesis is substantially equivalent to a legally marketed predicate device and is safe and effective for its intended use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2003

Karen A. Lindner, C.E.O.
Danmar Products, Inc.
221 Jackson Industrial Dr.
Ann Arbor, MI 48103

Re: K013452
Trade/Device Name: Cranial Adjustive Prothesis
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: MVA
Dated: October 15, 2003
Received: October 17, 2003

Dear Ms. Linder:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

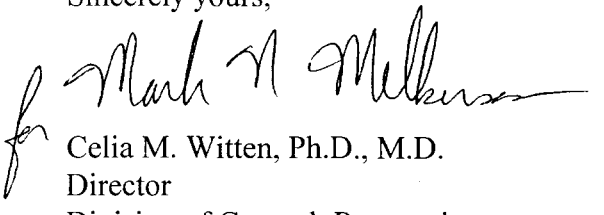
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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 Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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DEVICE NAME:

Danmar Products Cranial Adjustive Prosthesis

INDICATIONS FOR USE:

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for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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