510(k) SUMMARY K090341

Danmar Products, Inc.
Michigan Cranial Reshaping Orthosis

JAN - 6 2010

October 13, 2009

The following summary is provided pursuant to Section 513 (I) (3) (A) of the Federal Food Drug and Cosmetic Act:

Submitter Information:

Kay Fuller, RAC
VCI, LLC on behalf of
Danmar Products, Inc.
221 Jackson Industrial Drive
Ann Arbor, MI 48103

Contact Information:	Kay Fuller, RAC VCI, LLC 734-274-4680
Device Name:	Cranial Reshaping Orthosis
Proprietary Name:	Michigan Cranial Reshaping Orthosis
Common Name:	Cranial Helmet
Classification Name:	Cranial Orthosis
Classification Code:	OAN, Cranial Orthosis, Laser-Scan MVA, Cranial Orthosis 21 CFR §882.5970
Predicate Device Equivalence:	The Danmar Products Michigan Cranial Reshaping Orthosis is substantially equivalent to the Hanger Cranial Band, cleared for US commercialization via K072566 on January 9, 2008, the Boston Band Cranial Remolding Orthosis, cleared for US commercialization via K072862 on January 22, 2008 and the Michigan Cranial Helmet, cleared for US commercialization via K003630, May 29, 2001.
Device Description:	The Danmar Products Michigan Cranial Reshaping Orthosis a cranial orthosis that provides passive pressure to prominent regions of an infant's cranium to improve cranial symmetry and/or shape. It is fabricated from a positive mold, obtained from traditional manual casting methods or a 3-D scan of the infant's head, with front and rear sections that are comprised of

an inner, hypoallergenic, soft foam that is ⅛ " to ¼" thick, and an outer shell made of a, semi-rigid plastic. The Michigan Cranial Reshaping Orthosis is essentially identical to the predicate device known as the Danmar Products Michigan Cranial Helmet, (K003630) with exceptions only to the validated manufacturing improvements noted herein. The new manufacturing methods yield a substantially equivalent device as compared with the Danmar predicate device and manufacturing method.

Intended Use:

The Danmar Products Michigan Cranial Reshaping Orthosis is intended for prescription use to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape. A mold is made of the baby's head to create the orthotic. A plaster cast or a laser-scanning accessory may be used to create a scan of the infant's head to create the mold. The device is indicated for infants from 3 to 18 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 Michigan Cranial Reshaping Orthosis device incorporates the same technological characteristics as the legally marketed predicate devices noted in this Premarket Notification submission. The proposed fabrication changes noted in this submission include the addition of a 3-D shape capture method (Omega Scanner) and the Omega Carver. The Omega Scanner is labeled as a Class 1 Laser and therefore it may be utilized by a qualified user without eye protection when utilized under normal operating conditions. The finished subject device technological characteristics and principals of operations remain identical to the Danmar predicate device, noted herein. The following Tables illustrate the finished subject device remains identical to the Danmar predicate device (K003630).

SUBSTANTIAL EQUIVALENCE COMPARISON TABLE 1 MANUFACTURING METHODS			
steps	**Predicate Device Manual Process Steps**	**Subject Device Omega Process Steps**	**steps**
1	Orthotist makes negative mold of baby's head	Orthotist scans baby's head using Orthotist's Omega scanner	1
		Scan file modified by Orthotist, as needed for symmetry	2
2	Orthotist sends negative mold to Danmar	Orthotist sends scan file to Danmar electronically	3
3	Danmar makes positive plaster mold	Danmar carves positive foam plastic mold with Omega carver	4
4	Danmar modifies positive plaster mold according to Orthotist instructions		
5	Danmar wraps nylon stockinette over plaster mold	Danmar wraps nylon stockinette over foam plastic mold	5
6	Danmar fabricates orthosis according to conventional process	Danmar fabricates orthosis according to conventional process	6

SUBSTANTIAL EQUIVALENCE COMPARISON TABLE 2

Comparison Criteria	Subject Device	Predicate Device K003630	Predicate Device K072862	Predicate Device K072566
Product Code	OAN, MVA	OAN	OAN, MVA	OAN, MVA
Prescription Device	Yes	Yes	Yes	Yes
Indications for Use	*"The Danmar Products Michigan Cranial Reshaping Orthosis is intended for prescription use to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape. A mold is made of the baby's head to create the orthotic. A plaster cast or a laser-scanning accessory may be used to create a 3-D scan of the infant's head to create the mold. The device is indicated for infants from 3 to 18 months of age, with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic and brachycephalic shaped heads."*	*"The Danmar Products Michigan Cranial Helmet 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 and/or shape in infants from 3 to 18 months of age, with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic – and brachycephalic-shaped heads."*	*" The Boston Band Cranial Molding Orthosis is intended for medical purposes to passively hold prominent cranial regions of an infant's skull in order to improve cranial symmetry and/or shape in infants from three to eighteen months of age, with nonsynostotic positional plagiocephaly, including infants with plagiocephalic, brachycephalic and scaphocephalic patterned head shapes."*	*"Intended for medical purposes to apply static or gentle pressure to prominent regions of an infant's cranium to improve cranial symmetry or shape. To treat infants from three to eighteen months of age with moderate to sever non-synostotic positional plagiocephaly, including plagiocephalic, brachycephalic, scaphocephalic-shaped heads."*
Contraindications	Not for use in patients with craniosynostosis, scaphocephalic-shaped heads; hydrocephalus	Not for use in patients with craniosynostosis, hydrocephalus	Unknown	Unknown
Materials / Biocompatibility	Same/similar as Predicates	Hypo-allergenic, non-irritating and nontoxic inner foam lining; semi-rigid plastic outer shell	Hypoallergenic polyethylene foam; thermo-formable plastic	Hypoallergenic polyethylene foam; polypropylene copolymer outer shell

Summary of Device Evaluation:

The literature on this and similar predicate devices demonstrates that the Danmar Products Michigan Cranial Reshaping Orthosis performs as intended. Biocompatibility data demonstrates that the device's inner lining is non-irritating and nontoxic. The subject device validated fabrication modifications noted herein will yield a finished subject device equivalent to the Danmar predicate device (K003630). Performance testing results demonstrate that the device will not break or shatter when subjected to impact.

Conclusions:

Based on the above information and the information contained in this Premarket Notification, we conclude the Danmar Products Michigan Cranial Reshaping Orthosis is substantially equivalent to the noted legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Validation & Compliance Institute
c/o Ms. Kay Fuller, RAC
Regulatory Consultant, VCI, LLC
537 Fort Dearborn St.
Dearborn, MI 48124

JAN - 6 2010

Re: K090341
Trade/Device Name: Michigan Cranial Reshaping Orthosis
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: II
Product Code: MVA, OAN
Dated: December 12, 2009
Received: December 16, 2009

Dear Ms. Fuller:

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 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); 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 Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090341

Device Name: Michigan Cranial Reshaping Orthosis

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jeffrey Toy

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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