K012920

510(k) SUMMARY

NOV 2 8 2001

A. Applicant Information

Submitter: Fairview Orthopedic Laboratory, Fairview Rehabilitation Services, Orthotics and Prosthetics, Chicago Avenue Clinic, 910 E. 26th Street, Suite 400, Minneapolis, MN 55404

Contact: Carol Hentges, Certified Orthotist and Supervisor. Telephone: (612) 870-1208; Fax: (612) 870-1223

Date: [Date]

B. Device Name and Classification

Proprietary or Trade Name: Molded Cranial Helmet

Common or Usual Name: Cranial Orthosis

Classification Name: Cranial Orthosis (21 C.F.R. § 882.5970)

Predicate Device: DOC™ Band, Cranial Orthosis, K964992

C. Device Description

The Molded Cranial Helmet is a cranial orthosis used to treat children 3-18 months of age for moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

The Molded Cranial Helmet consists of a 1/8" light-weight, semi-rigid polypropylene outer shell and a ¼'' medium-density closed cell plastazote foam inner lining. The anterior inferior edge is trimmed just above the eyebrows, and the sides are trimmed above and around the ears. The posterior inferior is trimmed low to capture the occiput. A Velcro strap is attached on one side of the Helmet to keep it securely in place. The device allows for growth of the flattened areas of the infant's skull into the voids of the shell/foam lining, thus correcting the plagiocephaly and giving the infant's skull a more symmetrical shape.

The Molded Cranial Helmet is custom designed and custom-fit for each patient from a plaster mold of the infant's head. The mold is prepared by an orthotist using precise measurements of the infant's skull and plaster modification techniques. The orthosis is fabricated from the mold by lab technicians, with the trimming and final modifications performed by the orthotist. Precise fit and alignment are monitored by the orthotist during treatment.

D. Intended Use

The Molded Cranial Helmet is used to treat infants 3-18 months of age for moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads. The device is intended for medical purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape. The device is used by or on the order of a physician.

E. Comparison to the Predicate Device /Technological Characteristics

The Molded Cranial Helmet and the predicate device are very similar with respect to material, design, production, intended use, and special controls. Both devices consist of a plastic outer shell with a foam inner lining. Both devices are custom designed for infants 3-18 months of age, and are fabricated from custom-made plaster impressions of the infant's skull.

The most significant difference between the two devices is the material used for the foam inner lining. The predicate device uses a polyurethane foam inner lining, whereas the inner lining of the Molded Cranial Helmet is made from plastazote. Plastazote does not present new safety or effectiveness concerns, however. Plastazote is accepted in the industry as a material that can safely come into contact with skin and not cause severe redness, rash, or irritation. Plastazote is listed in the Material Safety Data Sheet, which describes plastazote as "polyethylene foam" and states that there are no skin exposure effects associated with its use.

F. Performance Data

The safety and efficacy of cranial orthoses, like the Molded Cranial Helmet, have been established by numerous tests and studies. Researchers studying the effects of treatment with cranial orthoses on infants with plagiocephaly, including Fairview orthotists, have concluded that the devices are effective in correcting plagiocephaly without evidence of relapse after treatment. A comprehensive assessment of cranial orthoses monitored the treatment of more than 750 infants over nearly ten years. Results recorded at the end of the treatment period and at 12, 18, and 24 month follow-ups documented complete or near complete correction of asymmetry. Fairview orthotists have experienced similar results, having treated infants for positional plagiocephaly and observing significant improvement in head shape with no adverse events.

The safety of the cranial orthosis is also established under biocompatibility assessments which reveal that the device is not expected to adversely affect infants under intended conditions of wear. The material used for the foam inner lining of the Molded Cranial Helmet, plastazote, is the only material on the device to come into contact with the skin and therefore is the only material that raises biocompatibility considerations. Plastazote is not reported to cause skin irritation or abrasion and is widely accepted in the industry as a safe material for skin contact. In addition, the safety of the device is further

evidenced by the fact that it is custom-designed and custom-fit for each patient, thus avoiding improper slippage or excessive pressure on the infant's cranium. Finally, the fit and function of the Molded Cranial Helmet are closely monitored by Fairview orthotists during treatment.

G. Labeling:

Labeling is provided with this 510(k) Summary.

H. Performance Standards:

There are no performance standards. Special controls are required. 21 C.F.R. § 882.5970; 63 Fed. Reg. 40,650-51 (July 30, 1998).

I. Published Literature:

1) Clarren SK, M.D. Plagiocephaly and Torticollis: Etiology, Natural History, and Helmet Treatment. J. of Pediatrics 1981; 98 (1): 92-95.

2) Ripley CE, et al. Treatment of Positional Plagiocephaly with Dynamic Orthotic Cranioplasty. J. Craniofacial Surgery 1994; 5 (3): 150-159.

3) Marshall D, M.D. Abnormal Head Shape in Infants. International Pediatrics, J. of Miami Children's Hospital 1997; 12 (3): 172-177.

4) Pollack IF, M.D. Diagnosis and Management of Posterior Plagiocephaly. Pediatrics 1997; 99 (2): 180-185.

5) Littlefield, TR et al. Treatment of Craniofacial Asymmetry With Dyanmic Orthotic Cranioplasty. J. Craniofacial Surgery 1998; 9 (1): 11-17.

6) Kelly KM, Ph.D. Importance of Early Recognition and Treatment of Deformational Plagiocephaly with Orthotic Cranioplasty. Cleft Palate-Craniofacial J. 1999; 36 (2): 127-130.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2001

Fairview Orthopedic Laboratory
Mr. Ross D'Emanuele
C/O Dorsey & Whitney LLP
Pillsbury Center South
220 South Sixth Street
Minneapolis, Minnesota 55402-1498

Re: K012920
Molded Cranial Helmet
Regulation Number: 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: MVA
Dated: August 27, 2001
Received: August 30, 2001

Dear Mr. D'Emanuele:

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 and additionally 809.10 for in vitro diagnostic devices), 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 Mark N Melkerson

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

Enclosure

510(k) Number (if known): K012920

Device Name: Molded Cranial Helmet

Indications For Use:

The Molded Cranial Helmet is used to treat children 3-18 months of age for moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads. The device is intended for medical purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape. The device is for use by or on the order of a physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

for Mark N Millum

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

510(k) Number K012920