JUL 1 8 2003

K 030669

510(k) Summary of Safety and Effectiveness

Submitter: D. Barry McCoy C.P.O. Northeast Orthotics and Prosthetics Inc. Rhode Island Hospital, 2 Dudley St., Providence, RI 02903 and Custom Composite Mfg. Inc. 170 Macklin St. Cranston, RI 02920
Contact: D. Barry McCoy C.P.O. Telephone (401) 275-2230 Fax 401-275-4901
Date: June 9, 2003

I. Classification: Class II
II. Common or Usual Name: cranial orthosis, cranial band, helmet, Molding helmet
III. Classification Name: Cranial Orthosis, Code MVA CFR 882.5970
IV. Predicate Device: Ballert Molding Helmet (K 011433)
V. Performance Standards: None, Special Controls required
VI. Description:
   A. The Providence Molding Helmet is a cranial orthosis used to treat moderate to severe non-synostotic positional plagiocephaly in children from 3 to 18 months of age. This includes infants with plagiocephalic-, brachyecephalic-, and scaphocephalic- shaped heads. This device works by applying gentle holding pressure to the prominent regions of the infant's skull while leaving room for growth in the adjacent flattened regions.
   B. The Providence Molding Helmet consists of a 5/32 polypropylene outer shell and two (2) layers of 3/16 volara foam inner lining. The helmet is split posteriorly and an elastic Velcro strap is attached to the back 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.
   C. The Providence Molding Helmet is custom designed and custom fitted for each patient from a plaster mold of the infants' head.
VII. Labels and Labeling: Labels and instructions for use are provided including precautions, and materials required by the special controls to which this product is subject.
VIII. Indications for Use: The Providence Molding Helmet is intended for medical purposes to improve cranial symmetry and/or shape. This device is prescribed by a physician to treat moderate to severe non-synostotic positional plagiocephaly in children from 3 to 18 months of age.
IX. Substantial Equivalence: The Providence Molding Helmet is substantially equivalent to the Ballert Molding Helmet (K 011433)
X. Clinical Review and Discussion: A review of the literature was provided.
XI. Indications for Use: The Providence Molding Helmet is a cranial orthosis used to treat moderate to severe non-synostotic positional plagiocephaly in children from 3 to 18 months of age. This includes infants with plagiocephalic-, brachyecephalic-, and scaphocephalic- shaped heads.
XII. Contraindications for Use: Infants with synostosis, or hydrocephalus.

(End of Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2003

D. Barry McCoy, C.P.O.
170 Macklin St.
Cranston, Rhode Island 02920

Re: K030669
Trade/Device Name: Providence Molding Helmet
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: MVA
Dated: June 19, 2003
Received: June 13, 2003

Dear Mr. McCoy:

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 Mark N. Melkerson

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

510(k) Number: K030669

Device Name: Providence Molding Helmet

Indications for Use:

The Providence Molding Helmet is used for treatment of children from three (3) to eighteen (18) months with moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads. The device is prescribed by a physician to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape.

Contradictions for Use: Infants with synostosis or hydrocephalus.

for Mark N Milkerson

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

510(k) Number K030669