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K021221
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510(K) SUMMARY

The following summary is provided in accordance with C.F.R. section 807.92.

A. APLICANT INFORMATION

- *Submitter:*
  Orthotic & Prosthetic Lab, Inc.
  748 Marshall Ave.
  Webster Groves, MO 63119

  Phone (314) 968-8555
  Fax (314) 968-0037

- *Contact:*
  Thomas L. Malone,
  Vice President of Administration
  Phone (314) 968-8555
  Fax (314) 968-0037

- *Summary Date:*
  April 17, 2002

B. DEVICE NAME AND CLASSIFICAITON

- *Common Name:*
  Cranial Molding Helmet

- *Classification Name:*
  Cranial Orthosis

- *Trade Name:*
  O&P Cranial Molding Helmet

- *Class:*
  Class II, Cranial Orthosis, Code MVA, CFR 882.5970

- *Predicate Device:*
  STARband Cranial Orthosis by Orthomerica Products (K011350)

C. DEVICE DESCIPTION

O&P Cranial Molding Helmets are custom made at the direction of a physician's prescription. Helmets are made by hand for each infant by taking a cast of the baby's head. The cast is filled with plaster and a positive mold of the infant's head is created. The flattened areas of the positive mold (corresponding to the flattened areas of the infants head) are then built up

and made round. The finished helmet has a hard middle layer with a padded inner and outer layer. There are ventilation holes in the top of the helmet and the helmet is held in place with a chinstrap.

O&P Cranial Molding Helmets work in two ways. The first way is that the helmet fits close to the head where the head sticks out, and loosely over the flattened area. The skull will grow into the loose area of the helmet, allowing the flattened parts of the head to "catch up" with the prominent areas. This type of helmet is known as a "passive" or "Clarren style" helmet. The second way the helmet is effective is by providing a rounded surface for the infant's head to lie on, removing the worry about proper positioning.

D. INTENDED USE

The O&P Cranial Molding Helmet 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 in infants from 3 to 18 months of age, with moderate to sever nonsynostotic positional plagiocephaly, including infants with plagiocephalic and brachycephalic shaped heads.

E. TCHNOLOGICAL CHARACTERISTICS COMPARISON

The O&P Cranial Molding Helmet and its predicate device have exactly the same purpose, are made from the same materials and work in exactly the same way. Both the O&P Cranial Molding Helmet and the Orthomerica STARband work by fitting close to the head where the head sticks out, and loosely over the flattened area. The infant's skull will grow into the loose area of the orthosis, allowing the flattened parts of the head to "catch up" with the prominent areas. The second way that both the O&P Molding Helmet and the predicate device work is by insuring that the infant is always lying on a rounded surface, removing the worry about proper positioning.

While the Orthomerica STARband is a "band" and the O&P Cranial Molding Helmet is a "helmet", both devices work on the same principals as describe in the above paragraph and function in the same way. The STARband is secured by means of a side-opening gap that is fastened with a Dacron strap over a bellow. The O&P Cranial Molding Helmet uses a padded Velcro chinstrap to secure the helmet to the infant's head. The use of a chinstrap and helmet combination is well documented and in use by companies already granted premarket approval by the FDA.

F. PERFORMANCE DATA

The O&P Cranial Molding Helmet is substantially equivalent to Orthomerica's STARband (K011350). As such, the O&P Cranial Molding Helmet meets the same standards of performance as the STARband and the OPI Band for which the STARband claimed substantial equivalence.

Prior to cranial orthoses being classified and for the last nineteen years, an area hospital department in St. Louis has used O&P Cranial Molding Helmets as an effective and safe means

of treating moderate to severe positional plagiocephaly. To date an estimated 4,256 infants have been treated with O&P Cranial Molding Helmets and they are now considered a routine part of the hospital's treatment plan for positional plagiocephaly.

Researchers studying the effects of treatment with cranial orthoses on infants have concluded that the devices are effective in correcting abnormal headshape, with evidence of relapse following treatment. The use of passive or Clarren style helmets dates back to the mid 1970's and their effectiveness is well documented in:

1. Clarren S, Smith D, Hanson J. Helmet treatment for plagiocephaly and congenital muscular toricollis. *Journal of Pediatrics* 1979;94:443
2. Clarren SK. Plagiocephaly and torticolis: etiology, natural history, and helmet treatment. Journal of Pediatrics 1981;98L92-95
3. Clarren SK, Smith DW. Congenital deformities. *Pediatr Clin North Am* 1977;24(4) : 665-667
   Persing J, Nichter L, Jane J, Edgerton M. Extenal cranial vault molding after craniofacial surgery. *Ann Plast Surgery* 1986; 17:274-283
4. Kane A, Mitchel L, Craven K, Marsh J. Observation on a recent increase in plagiocephaly without synostosis. *Pedatrics* 1996;97:877-885

The most comprehensive assessment of cranial orthoses monitored the treatment of more than 750 infants over a span of nearly ten years. Results were recorded at the end of the treatment period and again at 12, 18, and 24 month follow-ups. The study documented complete or near complete correction of asymmetry for a wide variety of head shapes. The details of this study can be found at:

5. Littlefield TR, Beals SP, Manwaring KH, Pomatto JK, Joganic EF, Golden KA, Ripley CE. Treatment of Craniofacial Asymmetry with Dynamic Orthotic Cranioplasty. *Journal of Craniofacial Surgery.* 1988; 11-17.

G. SUMMARY

The safety and effectiveness data submitted to the FDA establishes that the O&P Cranial Molding Helmet is safe and effective for its intended use and is substantially equivalent to applicable predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Thomas L. Malone
Orthotic & Prosthetic Lab, Inc.
748 Marshal Avenue
Webster Grove, Missouri 63119

JUL 1 2002

Re: K021221
Trade/Device Name: O&P Cranial Molding Helmet
Regulation Number: 21 CFR 890.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: MVA
Dated: April 17, 2002
Received: April 17, 2002

Dear Mr. Malone:

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 21 CFR Part 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 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

STATEMENT OF INDICATIONS FOR USE

K021221

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DEVEICE NAME: O&P Cranial Molding Helmet

INDICATIONS FOR USE:

Intended for medical purposes 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 plagiocehalic and brachycephalic shaped heads.

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

510(k) Number K021221