K063395

510(K) SUMMARY

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

A. APPLICANT INFORMATION

DEC 2 2 2006

- *Submitter:*

Orthotic & Prosthetic Lab, Inc.
748 Marshall Ave.
Webster Groves, MO 63119

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

- *Contact:*

Thomas L. Malone,
Chief Operating Officer
Phone (314) 968-8555
Fax (314) 968-0037

- *Summary Date:*
  November 1, 2006

B. DEVICE NAME AND CLASSIFICAITON

- *Common Name:*
  Cranial Molding Helmet

- *Classification Name:*
  Cranial Orthosis

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

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

- *Predicate Device:*
  Precision Prosthetic and Orthotics, Inc., Orthotic Molding Helmet (K013700)

C. DEVICE DESCIPTION

O&P Bivalve 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 creating a void. As the child's head grows, the skull is slowly reshaped and rounded by growing into the open voids created in the helmet for this purpose. The finished helmet has a foam-lined interior and has rigid plastic exterior. The helmet is bivalve with the anterior section overlapping the posterior section. The helmet is secured by means of a rivet on one side and an elasticized Velcro closure on the opposite side.

D. INTENDED USE

The O&P Bivalve 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, brachycephalic and scaphocephalic shaped heads.

E. TCHNOLOGICAL CHARACTERISTICS COMPARISON

The O&P Bivalve 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. When Precision Prosthetics and Orthotics, Inc. went out of business in October of 2006, O&P Lab hired their orthotist responsible for the design and fitting of their orthotic molding helmet. Both the O&P Bivalve Cranial Molding Helmet and the Precision Orthotic Molding Helmet 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 Bivalve 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.

F. PERFORMANCE DATA

The O&P Bivalve Cranial Molding Helmet is substantially equivalent to Precisions Orthotic Molding Helmet (K013700). As such, the O&P Cranial Molding Helmet meets the same standards of performance as Precision's Orthotic Molding Helmet and the DOC Band (K964992) for which the Orthotic Molding Helmet claimed substantial equivalence.

Prior to cranial orthoses being classified and for the last nine years, Precision Prosthetics treated over 2,340 children with their orthotic molding helmet as an effective and safe means of treating moderate to severe positional plagiocephaly. This same helmet is now being produced by Orthotic & Prosthetic Lab, Inc. using the helmets original designer and fabrication director.

Researchers studying the effects of treatment with cranial orthoses on infants have concluded that the devices are effective in correcting abnormal headshape, with no evidence of relapse following treatment. The use of passive cranial remolding orthosis dates back to the early 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 Bivalve Cranial Molding Helmet is safe and effective for its intended use and is substantially equivalent to applicable predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Orthotic & Prosthetic Lab, Inc.
% Mr. Thomas L. Malone
748 Marshall Avenue
Webster Groves, Missouri 63119

DEC 2 2 2006

Re: K063395
Trade/Device Name: O&P Bivalve Cranial Molding Helmet
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: MVA
Dated: November 1, 2006
Received: November 9, 2006

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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

Barbara Brechner

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063395

Device Name: O&P Bivalve Cranial Molding Helmet

Indications For Use: The O&P Bivalve 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 severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic, brachycephalic and scaphocephalic shaped heads.

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

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

Barbara Quiem

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K063395