K103362

AOI

Advanced OrthoPro, Inc.

APR 18 2011

AOI 510(K) Summary of Effectiveness and Safety

The summary contained hereinafter is provided pursuant to Section 513(I)(3)(A) of the Federal Food, Drug and Cosmetic Act.

A. Applicant Information

1. Submitter Name: Advanced OrthoPro Inc. (AOI)
2. Address: 1820 N. Illinois St., Indianapolis, IN 46202
3. Telephone: 317-924-4444
4. Contact Person: Keon Mansoori
5. Date Prepared: February 8, 2011
6. Registration Number:

B. Device Name and Classification

1. Name: Cranial Helmet
2. Trade Name: AOI Cranial Remolding Helmet
3. Common Name: Cranial Orthosis
4. Classification Name: Cranial Orthosis
5. Product Code: MVA
6. Class: II
7. Regulation Number: 21 CFR § 882.5970

C. Identification of Legally Marketed Devices
1. Name: OPIBand by Orthomerica
2. K Number: K001167
3. Date Cleared: July 7, 2000

D. Device Description

The AOI Cranial Helmet is a cranial orthosis which is made through a custom fabrication process to apply mild pressure to prominent regions of a young child's cranium to slow further growth in that area while allowing flattened portions of the cranium to grow into voids built into the helmet in order to improve overall cranial symmetry.

The helmet itself, once finished and delivered, covers the majority of the head and is trimmed as follows. The anterior inferior edge is trimmed just above the eyebrows, and the sides are trimmed above the ears. The posterior inferior is trimmed low to capture the occiput. A Velcro strap is attached to one side of the helmet to keep it

securely in place. The details of the materials used in this helmet and process are found below.

The AOI Cranial Helmet is not packaged for sale due to the fact that it is a custom fabricated device. The device is fitted to the child's head at the time of delivery. The AOI device has no accessories, and no options are available for the infant or the caregiver.

The AOI Cranial Helmet is custom made by first having a Certified Orthotist take a plaster mold of the patient's head. Since this device is custom fabricated for each patient there is no such thing as a standard size, model variance or otherwise. This individual's mold is then filled with plaster and a positive model of the child's head is made. The prominent areas are left alone on the model while the flattened areas of the model (which correspond to flat areas of the child's head) are built up with plaster to create rounded and symmetrical voids. As the child grows and the head fills the voids, which are made for just that purpose, the skull is slowly shaped into a more symmetrical shape. All steps of fabrication and production are done under the supervision of a Certified Orthotist.

The AOI Cranial Helmet is made of substantially the same materials as the predicate. The finished AOI Cranial Helmet is composed of a hard outer shell, made of thermoform-able plastic (Copolymer 5/32 inch) and an inner layer of polyethylene foam (1/2 inch). These materials are the exact same materials used on many types of medical devices and come into protracted contact with the skin of adults and children every day. Throughout the duration of use, the fit and alignment of the device are monitored by the Certified Orthotist on at least a bi-monthly basis at re-evaluation appointments. Instructions on the care and use of the device, including wearing schedule and helpful hints are provided to caregiver at time of delivery of the product. In addition to the evaluations by the Orthotist the AOI Cranial Helmet is only provided to person's with a prescription from their physician for the device, and therefore this device is also only provided to persons whom are under the care of a physician who has decided to apply this product. Please see the Figures below which show the AOI Cranial Helmet.

Figure 1	Figure 2
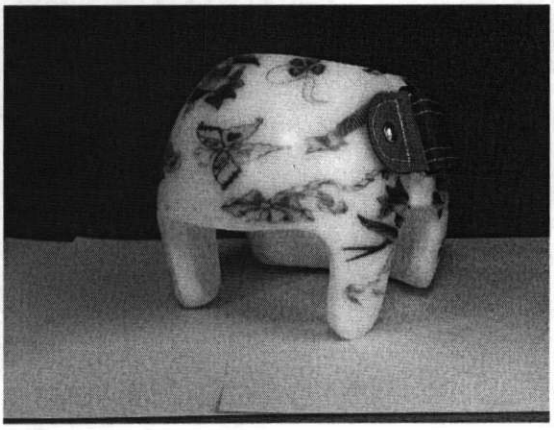	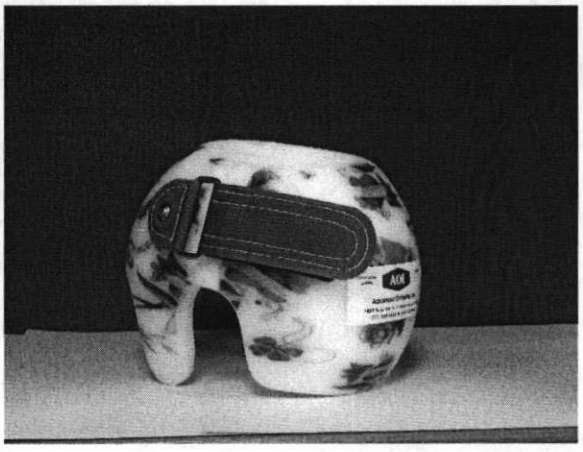
Figure 3	
	

E. Intended Use and Indications of Use

The AOI Cranial 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 age 3 to 18 months of age, with moderate to severe nonsynotic positional plagiocephaly, including infants with plagiocephalic- and brachycephalic-shaped heads.

F. Comparison to Predicate Device

The AOI Cranial Helmet and the predicate device it is based on are very similar with respect to the production processes, the instructions for use which are provided to the patient, the materials used to produce the items, safety and effectiveness and special controls used in production. In fact, the AOI Cranial Helmet and its predicate device have exactly the same purposes, are made from the same materials and work in exactly the same way, as will be shown below.

The material in the production of the AOI Cranial Helmet is handled in the exact same manner as the polymer used in the predicate, incorporating all of the safety and standards of practice. The proposed indications of use are analogous to those presented by the predicate device, and biocompatibility, function and effectiveness also closely shadow those of the predicate device.

Comparison Criteria	**Subject Device**	**Predicate Device (OPIBand K001167)**
Product Code	MVA	MVA
Prescription Device	YES	YES
Materials	1. Outer rigid shell made of 5/32 inch copolymer plastic. 2. Inner liner of 1/2 inch polyethelene foam. 3. 1 1/2 inch Dacron Strap. 4. 1 1/2 inch Chafe with roller loop. 5. Nylon Washer 6. Gap Block 1/2 inch firm pelite polyethelene foam.	1. Outer shell of 5/32 inch copolymer plastic. 2. An inner liner liner of 1/2 inch pelite polyethelene foam or Aliplast foam. 3. 1 1/2 in. Dacron Strap 4. Gap block 1/2 inch firm pelite polyethelene foam. 5. Nylon Washer
Product Design	Custom made cranial orthosis. approx. 6 oz.	Custom made cranial orthosis, approx 6 oz.
Production	1. Form orthosis from positive mold of infant's head.	1. Form orthosis from a positive mold of infant's head.

Comparison Criteria	Subject Device	Predicate Device (OPIBand K001167)
Indications for use	The AOI Cranial 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 age 3 to 18 months of age, with moderate to severe nonsynotic positional plagiocephaly, including infants with plagiocephalic- and brachycephalic- shaped heads.	"The OPIBand 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- and brachycephalic- shaped heads."
Contraindications	The AOI Cranial Helmet is not for use on infants with craniosynostosis or hydrocephalus.	"This device is not for use on infants with pre-surgical craniosynostosis or hydrocephalus."

See Table (supra)

G. Performance Data

The safety of cranial helmets has also been shown through past biocompatibility assessments which reveal that this type of device is not expected to adversely affect children under intended conditions of wear.[1] The AOI Cranial Helmet has not undergone its own individual clinical trials with respect to biocompatibility. This is in compliance with ISO 10993-1 in that after review of the production methods and materials involved "no testing is needed if the material has a demonstrable history of use in a specified role that is equivalent to that of the device under design." In the case of the AOI Cranial helmet the materials used in the manufacture and completed product are copolymer plastics and polyethelene foams that are used in devices which are used directly against the skin of children and even infants. Devices such as custom night AFOs or custom made Cervical devices are fabricated using the same methods and materials and contact the skin for protracted wear periods. They are prepared using the same vacuum forming and glueing method. The only surface contacting the skin is the foam. These materials are provided to AOI by companies which certify that their

[1] 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.

products are manufactured and delivered in a manor which is compliant with ISO standards.[2]

Importantly, the only part of the device which contacts the patient's skin is the foam liner which is made of polyethelene foam. This foam is not reported to cause skin irritation or abrasion and is used widely in the medical device field as a safe interface between derma and device. Also, the safety of these helmets is furthered by the fact the each device is custom made to the individual patient, this prevents excessive slipping or migration of the helmet or excessive pressure on the child's cranium. Most importantly all patients wearing helmets are closely monitored by AOI personnel who are certified and have had years of experience as orthotists, including bi-monthly evaluations of the helmet and patient and an open dialogue with the treating physicians and caregivers. Also, the proposed device is not in any quantifiable way different from the predicate device with regard to manufacture or materials used, thus when looking at the predicate device we can see that the helmet has been effectively used for years without complications of this sort.

H. Summary

As can be seen from the 510(K) Summary supra the proposed AOI Cranial Helmet does not differ substantially from the predicate device. The predicate is made of the same materials and in the same fashion as the AOI proposed device. Based on a comparison of the technological specifications of the predicate device and the AOI Cranial Helmet it is believed that the AOI Helmet has been shown to be substantially equivalent to the predicate device.

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[2] O&P Enterprises, Inc. and American Plastics Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Advanced OrthoPro, Inc.
c/o Keon Mansoori B.A., J.D.
Counsel
1820 N. Illinois St.
Indianapolis, IN 46202

Re: K103362
Trade/Device Name: AOI Cranial Helmet
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: MVA
Dated: February 15, 2011
Received: February 15, 2011

APR 18 2011

Dear Mr. Mansoori:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for 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

510(k) Number (if known): K103362

Device Name: AOI Cranial Helmet

Indications for Use:

The AOI Cranial 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 age 3 to 18 months of age, with moderate to severe nonsynotic positional plagiocephaly, including infants with plagiocephalic- and brachycephalic- shaped heads.

Prescription Use
___X____
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

JEFFREY TOY

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K103362