K111247

Orthotic Care Services, LLP

AUG 15 2011

510(k) Summary of Effectiveness and Safety

The following summary is provided pursuant to 510(k) summaries specified in 21 CFR 807.92(a) of the Federal Food, Drug, and Cosmetic Act.

1.) Applicant Information:

Submitter and Contact:
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Summary Date: April 21, 2011

Subject: K111247

2.) Classification and Device Name

Type: Traditional 510(k) Submission

Proprietary Name: Cranial Remolding Orthosis

Common Name: Cranial Orthosis

Classification: Class II, Cranial Orthosis, Code MVA

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

3.) Predicate Devices: STARband Cranial Remolding Orthosis (K082950/K011350) *510(k) submitter:* Orthomerica Products Inc, 505 31st Street, P.O. Box 2927, Newport Beach, CA 92659, Telephone: (949) 723-4500, Facsimile: (949) 723-4501

4.) Device Description

The Cranial Remolding Orthosis is prescribed for use on infants between 3-18 months with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic, scaphocephalic, and brachycephalic-shaped heads by applying pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape. The Cranial Remolding Orthosis is also prescribed for use following minimally invasive surgery for infants between 3-18 months with craniosynostosis who still need moderate to severe correction of plagiocephali-shaped, brachycephalic-shaped, and/or scaphocephalic-shaped heads.

Commonly diagnosed head deformities are positional plagiocephaly, brachycephaly (head is disproportionately wide and flat posteriorly), and scaphocephaly (head is disproportionately long and narrow). In addition, the Cranial Remolding Orthosis can be used following a minimally invasive surgery for infants with craniosynostosis who still need moderate to severe correction of plagiocephaly, brachycephaly and scaphocephaly. They are less common but represent an emerging patient group.

Plagiocephaly, Brachycephaly and Scaphocephaly:

This condition is defined as a malformation of the skull resulting in an "oblique", "crooked", or "parallelogram" shaped head. Other similar conditions which are positional in nature are Brachycephaly and Scaphocephaly, and they result in heads that are well out of proportion to the normal width versus length. Medically diagnosed non-synostotic deformational plagiocephaly is typically assessed by a combination of clinical observation, x-ray, CT scan, and possibly an MRI to rule out craniosynostosis.

Craniosynostosis:

This conditions is caused by the premature fusion of one or more cranial sutures of the skull; causing the head to grow into a usual shape. It presents in a dissimilar way to deformational (positional) plagiocephaly. However, in cases where the physician cannot make a definitive diagnosis, patients are referred to specialists such as neurosurgeons or craniofacial surgeons. These specialists will order a test such as a CT scan or MRI to confirm the diagnosis of craniosynostosis.

Following surgery to release the diseased suture, the same principles that guide cranial remolding of deformational head shapes are applicable. A prescription will be provided if the craniofacial surgeon deems that a helmet is medically necessary. In both deformational head shapes and post-surgical head shapes the Cranial Remolding Orthosis is designed to maintain total contact over the areas where growth is not desired while providing space over areas where growth is desired.

Causes:

Cranial asymmetries or disproportions are commonly caused by external forces to the head and are influenced by many differing factors that include supine sleeping positions (Back to Sleep campaign in 1992), preferred head orientation, torticollis (limited head rotation), increased incidence of multiple births, low tone (hypotonia), and extended supine positioning.

Function of Device:

The device allows for growth of the flattened areas of the infant's skull into the voids within the shell and foam lining. This combination of total contact and relief allows for significant correction of the asymmetrical head shape; thereby giving the infant's skull a more symmetrical and/or proportioned shape.

Material Specifications:

The Cranial Remolding Orthosis is fabricated from a 3/16" co-polymer base plastic shell with a ½" foam interface liner. The type of material used on the foam interface liner is Pelite polyethylene foam, Plastazote, or Aliplast foam. A ½" foam spacer fills a ½" side opening, opposite the deficit, utilizing the same material as the corresponding foam liner. 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 distally to capture the occiput. A hook and loop closure (also referred to as Velcro within the industry) is attached on the side of the deficit, bridging over the side opening, keeping the device securely in place.

Materials	• 3/16" outer shell of copolymer plastic • ½" hypoallergenic polyethylene foam (Pelite, Plastazote or Aliplast) • 1 1/2" strap of dacron • 1 1/2" chafe buckle • Large flange, blind rivet or 89X speedy rivet • ½" hypoallergenic polyethylene foam spacer (Pelite or Aliplast)

5.) Intended Use of Device

The Cranial Remolding Orthosis is prescribed for use on infants between 3-18 months with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic, scaphocephalic, and brachycephalic-shaped heads, by applying pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape. The Cranial Remolding Orthosis is also prescribed for use following minimally invasive surgery for infants between 3-18 months with craniosynostosis who still need moderate to severe correction of plagiocephali-shaped, brachycephalic-shaped, and/or scaphocephalic-shaped heads.

6.) Comparison to Predicate Device

The Cranial Remolding Orthosis is a custom orthosis used to treat an infant's abnormally shaped head from three to eighteen months of age. This condition is clinically known as positional or deformational plagiocephaly. The Cranial Remolding Orthosis contains and limits growth of these bossed and protruding areas while promoting growth of the flattened areas of the skull as facilitated by the voids and spaces created within the helmet. The Cranial Remolding Orthosis is only available when prescribed by a physician, a certified pediatric nurse practitioner or other qualified medical professional.

The Cranial Remolding Orthosis' design has been illustrated in Table 5.1 below. There is not a significant difference between the helmets' materials selections, and the processes for fabrication are substantially equivalent. The inner liner is made with hypoallergenic polyethylene foam. These materials can safely come into contact with the skin and not cause redness, rash or irritation. A speedy rivet or pop-rivet will be used to attach the strap and chafe

to the Cranial Remolding Orthosis. The rivet system used provides a cosmetically appealing product.

Similarities in the Cranial Remolding Orthosis and the STARband device are design, production, intended use and special controls. Both devices consist of outer plastic shells and an inner foam lining. The materials used and processes of manufacturing the device are handled in an identical manner to the predicate device, incorporating all the safety and standards of practice. The proposed indications of use, biocompatibility, function and effectiveness are equivalent to those presented by the predicate device.

Table 5.1 – Cranial Remolding Orthosis Design vs. STARband

	Cranial Remolding Orthosis	**STARband**
Intended Use	Maintains total contact over areas of bossing or protrusion and creates voids over areas of depression or flattening to redirect cranial growth toward greater symmetry.	Maintains total contact over areas of bossing or protrusion and creates voids over areas of depression or flattening to redirect cranial growth toward greater symmetry.
Materials	• 5/32" outer shell of copolymer plastic • ½" hypoallergenic polyethylene foam (Pelite, Plastazote or Aliplast) • 1 1/2" strap of dacron • 1 1/2" chafe buckle • Large flange, blind rivet or 89X speedy rivet • ½" hypoallergenic polyethylene foam spacer (Pelite or Aliplast)	• Outer shell of .156 copoly plastic • An inner liner of ½" Pelite polyethylene foam or ½" Aliplast foam. • A strap of 1 ½" Dacron • A 1 ½" chafe buckle • Large Flange, Blind Rivet • A Gap Block made from ½" firm pelite polyethylene foam • A nylon washer
Product design	Custom fabricated cranial remolding orthosis Approximate weight: 6oz.	Custom made cranial orthosis, approx 6oz. in weight
Production	Form orthosis from a positive mold of the patient's head: • A positive scanned model is captured using the Willow Wood Omega Scanner. • A 3-dimentional model is carved using a 5-axis routing machine carver in-house and/or a central fabrication site prior to modification and fabrication of the device. • The 3-dimentional model is modified by a technician under the direction of a clinician. Plaster buildups are added to areas of flattening to create symmetry and/or proper proportions of the head.	• Form orthosis from a postitive mold of infant's head. • Postitive mold is formed based upon measurements of the infant's head taken by the STARscanner, which a 3-dimensional image is made or from a traditional plaster cast. • The 3-dimensional image is used to produce a postitive mold using a 5-axis routing machine.

Comparison of Willow Wood OMEGA Scanner vs. STARscanner

The predicate STARScanner and the OMEGA Scanner are equivalent in many ways. They both achieve the same result through slightly different means while maintaining the highest levels of safety for the patient. Both scanners are Class I FDA approved laser imaging devices that provide a 3D digital image of the patient's head that is accurate to .5mm. The both used the same computer OMEGA Tracer Software. The STARScanner uses eight cameras and four lasers to capture the image, while the OMEGA Scanner uses two cameras, one laser, and reflective stickers to capture an image that is just as accurate. The accuracy, reproducibility, and repeatability of the STARScanner and the OMEGA scanner were evaluated by scanning three cylindrical shapes five times and downloading the files three times to the digital image. Standard measurement system statistical process control procedures were used to evaluate the scan rate of error, standard deviation, repeatability, and reproducibility of multiple scans. Both devices met the predetermined acceptable criteria. Both devices are approved by the FDA to be used in scanning an infant. No eye protection is necessary as the FDA as deemed these devices as Class 1 lasers.

There are some differences between the STARScanner and the OMEGA scanner. One of the major differences between the two devices is that the predicate STARScanner is much less portable than the OMEGA scanner is; with the STARScanner the patient laying on a sled type table and has the measurement devise passed over the patients cranium when they are laying in the appropriate position. This requires the infant to lay as still as possible. The OMEGA scanner takes it readings by waving the hand wand around the infant's reflective cap; the patient can be held or sitting up.

6.)Performance Standards and Data

The predicate device designed by Orthomerica (K011350) using the same techniques and materials. It incorporates an outer copolymer shell lined on its interior with a medium durometer cross linked polyethylene foam: Pelite or Volara (AliPlast) lining. (Orthomerica Products, Inc. Retrieved April 4, 2011 from http://www.orthomerica.com/products /cranial/starband.htm).

Description of Orthosis:

- Side-opening helmet
- Proximal opening
- 3/16" Copolymer shell
- ½" Polyethylene foam liner
- 1 ½" Velcro® strap and chafe closure

The safety of the cranial orthosis has been demonstrated through past biocompatibility assessments which revealed that this type of device is not expected to adversely affect children under intended conditions of wear/use. Though, our Cranial Remolding Orthosis has not undergone its own individual clinical trials with respect to biocompatibility. This is in compliance with ISO 10993-1[1] in that after review of the production methods and materials involved, "no testing is needed if the material has a demonstrated history of use in a specified role to that of the device under design."

These assessments reveal that the device and the materials used are not expected to adversely affect the infants under the intended conditions of wear.[2] The materials are not reported to cause skin irritation or any toxic effects. Furthermore, it is designed to avoid improper migration or harmful levels of pressure. The interior of the device is smooth and poses no threat to the child during application within the normal scope of its intended use.

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.

Special controls are required. 21 C.F.R. § 882.5970; 63 Fed. Reg. 40, 650-651 (July 30, 1998)

1 http://www.iso.org/iso/iso_catalogue.htm
2 Littlefield TA, Beals **S**, Manwaring KH, Pomnatto **JK**, Joganic **EF**, Golden KA, Ripley **CE**. Treatment of Craniofacial Asymmetry with Dynamic Orthotic Cranioplasty. *Journal of Cranio facial Surgery, **1988;*** **11-17.**

7.) Summary

The safety and effectiveness data submitted to the FDA establishes that the Cranial Remolding Orthosis is substantially equivalent to applicable predicate devices. Based on the technological characteristics and performance testing the device has been determined to be substantially equivalent to the predicate devices.

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

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AUG 15 2011

Re: K111247
Trade/Device Name: Cranial Remolding Orthosis
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: MVA
Dated: June 17, 2011
Received: June 24, 2011

Dear Mr. Hinshon:

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,

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

Indications for Use

510(k) Number (if known): **K111247**

Device Name: **Cranial Remodeling Orthosis**

Indications For Use:

The Cranial Remolding Orthosis is prescribed for use on infants between 3-18 months with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic, scaphocephalic, and brachycephalic-shaped heads, by applying pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape. The Cranial Remolding Orthosis is also prescribed for use following minimally invasive surgery for infants between 3-18 months with craniosynostosis who still need moderate to severe correction of plagiocephali-shaped, brachycephalic-shaped, and/or scaphocephalic-shaped heads.

Prescription Use ___X___ 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

KRISTEN BOWSHER

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K111247