510(k) Summary

DEC 0 5 2008

I. Applicant Information

- Applicant's Name and Address: Orthomerica Products Inc, 505 31st Street, P.O. Box 2927, Newport Beach, CA 92659, Telephone: (949) 723-4500, Facsimile: (949) 723-4501

  FDA Establishment Registration Number 1058152

- Contact: David C. Kerr, Chief Executive Officer, Telephone: (949) 723-4500, Facsimile: (949) 723-4501

- Submission Correspondent: Alan T. Sandifer, Director of Research and Development, 6333 North Orange Blossom Trail, Orlando, FL 32810, Telephone: (407) 290-6592, Facsimile: (407) 290-1303, asandifer@orthomerica.com

- Summary Date – October 1, 2008

II. Submission Information

- Type: Traditional 510(k) Submission
- Proprietary Name: STARband
- Common Name: Cranial Orthosis
- Classification: Class II (special controls); OAN; 21 CFR 882.5970
- Classification Name: Cranial Orthosis
- Predicate Devices: STARband, Cranial Orthosis, K011350
  STARlight Cranial Orthosis, K081994

III. Manufacturing Site: 6333 North Orange Blossom Trail, Orlando, FL 32810, Telephone: (407) 290-6592, Facsimile: (407) 290-2419, FDA Establishment Registration Number 1058152

IV. Description of Device

The STARband redirects the head growth to improve proportion and symmetry. The practitioner takes a plaster impression or scan of the baby's head to acquire the existing shape. The mold is sealed and filled with plaster or the scanned shape is carved from a rigid polyurethane foam blank to create a positive model of the head shape. The positive model is modified to obtain greater symmetry and space in the areas of flattening. The STARband provides total contact over the prominent or bossed areas of the baby's head to discourage growth there. Over the course of treatment, the inside of the band is modified further by the practitioner to provide space for growth to occur in the flat or depressed areas. The shape of the STARband directs growth into the areas of least resistance and creates a precise pathway for the head shape to improve in symmetry and proportion.

The STARband as it was released in K011350 is essentially still the same device. The STARband consists of a 5/32" outer copolymer shell with an inner liner made of ½" pelite polyethylene foam. There is a top opening and a side opening. The strap across the side opening is 1 ½" Dacron and Velcro and is attached to the STARband with a chafe and loop. A ½" pelite polyethylene foam gap block fills any gap in the side opening. Since the original clearance, a variation of the STARband has been released. It is identical in design; however, the inner liner is made of 1/2" Aliplast foam (closed cell polyethylene).

V. Statement of Indications and Intended Use

Statement of Indications:

The STARband is intended for medical purposes for use on infants from three to 18 months of age, with moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and/or shape. The device is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

Intended Use:

The STARband is design to treat infants with abnormal head shapes from age 3 months to 18 months and is available by prescription only. Since growth is the driving factor in head shape correction, the infants wear the STARband for approximately 23 hours per day. The most common head deformities are positional plagiocephaly, brachycephaly, and scaphocephaly. However, due to new minimally invasive surgical techniques for infants with craniosynostosis, post-surgical plagiocephaly, brachycephaly, and scaphocephaly are emerging as a growing patient group.

Craniosynostosis is caused by the premature fusion of one or more cranial sutures of the skull, causing the head to grow into an unusual shape. Some types of craniosynostosis have a clinical presentation similar to deformational (positional) plagiocephaly. Therefore in cases where the physician cannot make a definitive diagnosis, patients are referred to specialists such as neurosurgeons or cranio-facial surgeons. These specialists will order a test like a CT scan or MRI to confirm the diagnosis of craniosynostosis. If a baby has craniosynostosis, surgery is indicated to realign the plates of the skull and allow normal brain and skull growth to occur.

In general, the first year of life is the optimum time frame for surgical correction since infants are growing at such an accelerated rate during that time. No matter which surgical technique is used, the end result is a patient with no fused sutures. At this point the same principles that guide cranial remolding of deformational head shapes are applicable. In both deformational head shapes and post-surgical head shapes the STARband is designed to maintain total contact over areas where growth is not desired, and allow for space over areas where growth is desired. The STARband provides a pathway for the baby's head growth, directing it toward a more normal shape.

VI. Summary of Technological Characteristics

The proposed changes involve the indications for use and how the infants head shape is captured. Despite these changes the STARband cranial orthosis design will remain the same. However, there have been changes made to the STARband through the Orthomerica Engineering Change Order process that were minor and determined to not require a 510(k) submission. The following table illustrates the minor differences between the cleared device (K011350) and the device as it is currently marketed.

Table 1 – Comparison of Predicate Device cleared in K011350 to currently marketed device
Note: No changes will be made to the current device as a result of the proposed indications and shape capture change in this submission

Feature	From K011350	Current Product
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	- Outer shell of .156 copoly plastic - An inner liner of ½" pelite polyethylene foam - A strap of 1 ½" Dacron - A 1 ½" chafe buckle - A 91X speedy rivet - A bellows made from 1/16" firm pelite polyethylene; - A nylon washer	- 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 made cranial orthosis, approx 6oz. in weight	Custom made cranial orthosis, approx 6oz. in weight
Production	- Form orthosis from a positive mold of infant's head - Positive mold is formed based upon measurements of the infant's head taken by the STARscanner from which a 3-dimensional image is made or from a traditional plaster cast - The 3-dimensional image is used to produce a positive mold using a 5-axis routing machine	- Form orthosis from a positive mold of infant's head - Positive mold is formed based upon measurements of the infant's head taken by the STARscanner, the OWW Omega Scanner from which a 3-dimensional image is made or from a traditional plaster cast - The 3-dimensional image is used to produce a positive mold using a 5-axis routing machine

In reference to the technological characteristics, the inclusion of the Ohio Willow Wood (OWW) Omega Scanner is the main difference and is located under the production section of the table. Like the STARscanner Laser Data Acquisition system cleared with the original STARband (K011350), the OWW Omega Scanner is a class 1 laser device and as such is safe for use without eye protection under all normal operating conditions. The OWW Omega Scanner is a handheld scanner consisting of two cameras, one laser, and eight LED lights. Through testing, the OWW Omega Scanner was found to be safe and effective.

In addition, there are three minor changes indicated in the table: The inner liner may be made with either pelite polyethylene foam or Aliplast foam, the speedy rivet used to attach the strap and chafe to the STARband has been changed to a pop-rivet, and the bellows used to fill the side opening gap has been changed to a solid foam block. The Aliplast foam option was added at the request of Orthomerica's customers after biocompatibility testing and pressure distribution testing to confirm its equivalence to the pelite polyethylene foam. There are no clinical advantages or disadvantages to using Aliplast foam; however some customers were more experienced with Aliplast foam than Pelite foam and requested the switch. The speedy rivet was changed to the pop-rivet so that the inner liner of the band would be completely smooth and blemish free against the baby's head. The bellows device served an important purpose of bridging the gap in the side opening; however, it was found to be cumbersome for parents to deal with on a daily basis. The solid foam gap block is much easier to manage and is customizable by the practitioner for the best fit on the baby. The foam gap block is attached to the strap with Velcro.

The STARband is also substantially equivalent to the STARlight cranial orthosis (K081994). Although the materials may differ between the orthoses, the same intended use, underlying operating principles, and production processes apply.

Table 2 – Comparison of Predicate Device cleared in K081994 to currently marketed device

Note: No changes will be made to the currently marketed device as a result of the proposed indications and shape capture change in this submission

Feature	From K081994 (STARlight)	Current Product
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	Material for STARlight Side Opening, STARlight Bi-Valve, STARlight Cap - 5/32" - 1/4" clear Surlyn or 1/8" – 7/32" Clear Co-Polyester plastic shell Material for STARband Bivalve - Outer shell of 5/32" copolymer plastic - An inner liner of 1/2" pelite polyethylene foam Closure for Bivalve design - Sliding/Overlap closure system - Chicago screw (or similar) for tope sliding mechanism - 1" velcro strap - 1" chafe buckle - 91X speedy rivets Closure for Side Opening design: - 1" Velcro Strap	- 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 made cranial orthosis, approx 7 to 10oz. in weight	Custom made cranial orthosis, approx 6oz. in weight
Production	- Form orthosis from a positive mold of infant's head - Positive mold is formed based upon measurements of the infant's head taken by the STARscanner from which a 3-dimensional image is made or from a traditional plaster cast - The 3-dimensional image is used to produce a positive mold using a 5-axis routing machine	- Form orthosis from a positive mold of infant's head - Positive mold is formed based upon measurements of the infant's head taken by the STARscanner, the OWW Omega Scanner from which a 3-dimensional image is made or from a traditional plaster cast - The 3-dimensional image is used to produce a positive mold using a 5-axis routing machine

VII. Summary and Conclusions of Non-Clinical Performance Data

The STARband cranial orthosis has been used successfully in clinical practice since its original clearance in 2001. The minor changes mentioned in the preceding technical characteristics section involved standard orthotic fabrication and materials that have undergone biocompatibility testing. However, the STARscanner™ Data Acquisition System used to capture the infant's head shape has had minor technical changes and with due diligence performance testing was conducted. The changes made to the STARscanner were to improve ease of use for the practitioner and to update components to the state of the art.

In addition, the OWW Omega Scanner was evaluated for safety and efficacy. The primary safety issue is the laser. The STARscanner and the OWW Omega Scanner are both class 1 laser devices and as such are inherently safe for use without eye protection under all normal operating conditions. The effectiveness of each scanning device was evaluated through accuracy, reproducibility, and repeatability testing.

The accuracy, reproducibility, and repeatability of the STARscanner was evaluated by scanning three different cylindrical shapes (100mm, 125mm, 150mm diameters) five times at five different positions within the scan volume. Standard measurement systems statistical process control procedures were utilized to evaluate STARscanner errors, error standard deviations, repeatability of multiple scans, and reproducibility of multiple scans at multiple locations within the scan volume. The OWW Omega Scanner was evaluated by scanning three different cylindrical shapes (100mm, 125mm, 150mm diameters) five times while in random motion. These 15 scan files were then converted to .aop files 3 times to create a total of 45 scan files. Standard measurement systems statistical process control procedures were utilized to evaluate scan errors, error standard deviations, repeatability of multiple scans, and reproducibility of multiple scans in random motion.

Each device met the predetermined acceptance criteria and was found acceptable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Orthomerica Products, Inc.
% Mr. Alan T. Sandifer
Director of Research and Development
6333 North Orange Blossom Trail
Orlando, Florida 32810

Re: K082950
Trade/Device Name: STARband®
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial orthosis
Regulatory Class: II
Product Code: OAN, MVA
Dated: October 2, 2008
Received: October 3, 2008

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Dear Mr. Sandifer:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Statement of Indications for Use

510K Number (if known): K082950

Device Name: STARband®

Indications for Use:

The STARband is intended for medical purposes for use on infants from three to 18 months of age, with moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and/or shape. The device is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and 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)

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

510(k) Number K082950