510(k) Summary

JUN 10 2013

I. Applicant Information

Name:	Orthomerica Products, Inc.
Address:	6333 North Orange Blossom Trail Orlando, FL 32810
Telephone:	(407) 290-6592
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FDA Establishment Registration Number

1058152

Contact Information

Contact Person:	David Hooper, Manufacturing Engineer
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Date Prepared:	December 21, 2012

II. Submission Information

Type:	Special 510(k) Submission
Proprietary Name:	STARband®
Common Name:	Cranial Orthosis
Classification:	Class II (special controls); OAN; MVA; 21 CFR 882.5970
Classification Name:	Cranial Orthosis

III. Manufacturer Site

Name:	Orthomerica Products, Inc.
Address:	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/Modification

The STARband redirects the head growth to improve proportion and symmetry. The practitioner takes a plaster impression or a 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 using 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 K082950 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 or 1/2" Aliplast foam (closed cell polyethylene). 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. The proposed device modification is the addition of a new shape capture method, specifically the scanGogh-II™ by Vorum Research, Inc. This scanner uses one laser and one camera to capture shape data.

V. Statement of Indications and Intended Use

Statement of Indications:

The STARband is intended for medical purposes for use on infants from 3 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 3 to 18 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 designed 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. The STARband has also been cleared to treat unresolved head deformities in patients who have undergone surgery to correct craniosynostosis. The same principles of cranial remolding apply to positional deformities and post-operative patients.

VI. Predicate Devices

- STARband, Cranial Orthosis, K082950
- Boston Band Cranial Remolding Orthosis, K072862
- CAMLab Cranial Orthosis Helmet, K081787
- Boston Band, K111609

VI. Summary of Technological Characteristics

The modification proposed is the use of an additional tool which can be used to capture the infants head shape; the technological characteristics and the underlying principles of operation of the STARband Cranial Orthosis will remain exactly the same. This table illustrates that the device will in fact remain the same.

Table 1 – Comparison of Predicate Device cleared in K082950 to the proposed device

Feature	From K082950	Proposed Device
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 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	- 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, or 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	- 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, or the scanGogh-II 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
Testing	Repeatability and Reproducibility (R&R) Analysis - Utilized uniform shapes with known dimensions that represent various sizes of pediatric patients between ages 3 to 18 months of age - Compared proposed device to cast and predicate device - Associated parameters includes A-P and M-L - Proposed device is substantially equivalent to predicate device	Repeatability and Reproducibility (R&R) Analysis - Utilized uniform shapes with known dimensions that represent various sizes of pediatric patients between ages 3 to 18 months of age - Compared proposed device (scanGogh-II) to cast and predicate device - Associated parameters includes A-P and M-L - Proposed device is substantially equivalent to predicate device Cranial Shape Capture Accuracy Study - Utilized a representative cranial shape that possesses a predefined shape with known dimensions - Compared proposed device (scanGogh-II) to cast and predicate device - Associated Coordinate Planes (A-P; M-L; P-D and various Radius Parameters; Squareness; Flatness) - Proposed device is substantially equivalent to predicate device. Eye Shield Fit Assessment - A specific eye shield would properly fit infants - Assess coverage, fit and effectiveness - Proposed eye shields pass the assessment and provide safe and effective protection

The inclusion of the scanGogh-II is the focus of this submission. Additional testing was performed on the scanGogh-II to ensure substantial equivalence, that change is indicated in **Table 1** under the testing section. **Table 2** shows the additional accuracy testing

performed and the comparison results of the scanGogh-II. The term Pass within Table 2 indicates the scanGogh-II accuracy performed superior to the Cast method.

Table 2 – scanGogh-II Accuracy Comparison Summary

	Proximal Radius	Proximal Anterior Radius	Anterior Radius	Anterior Posterior Length	M-L Width Anterior	M-L Width Posterior	Posterior Panel Flatness	Lateral Panel Flatness	L-P Panels Square	Medial Panels Flatness	M-P Panels Squares
scanGogh-II vs. Cast Cranial Head Shape	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

The actual scanner wand hardware (camera and laser included) of the scanGogh-II is also known as the Fastscan Handheld Laser Scanner by Polhemus, Inc. The Fastscan Scanner has already received FDA clearance as part of other Cranial Remolding Orthosis 510(k) submissions, by Boston Band Cranial Remolding Orthosis (K072862 and K111609) and the CAMLab Cranial Orthosis Helmet (K081787). These submissions used the STARband (K011350 and K082950) as their predicate device and given that the technological characteristics are the same as the proposed device, these devices are all substantially equivalent.

VII. Summary and Conclusions of Non-Clinical Performance Data

The STARband Cranial Orthosis has been successfully used in clinical practice since its original clearance in 2001. The scanGogh-II is the only proposed change. The scanGogh-II was evaluated through accuracy, reproducibility and repeatability testing. The shape capture repeatability and reproducibility was evaluated and determined to be acceptable. An additional, Cranial Shape Capture Accuracy Study was performed concluding that the scanGogh-II yields a safe and effective product that is substantially equivalent to the predicate device. An Eye Shield Fit Assessment showed the eye shields were an acceptable fit for infants, providing safe and effective protection of the infant's eye during scanning. With sufficient accuracy and proper laser safety procedures, the scanGogh-II was determined safe and effective for scanning infants for STARband Cranial Orthosis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

June 10, 2013

Orthomerica Products, Inc.
c/o Mr. David L. Hooper
Manufacturing Engineer
6333 North Orange Blossom Trail
Orlando, FL 32810

Re: K124023
Trade/Device Name: STARband® Cranial Orthosis
Regulation Number: 21 CFR 882.5970
Regulation Name: Laser Scan Cranial Orthosis
Regulatory Class: Class II
Product Code: OAN
Dated: April 22, 2013
Received: April 23, 2013

Dear Mr. Hooper:

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,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K124023

Device Name: STARband® Cranial Orthosis

Indications For Use:

The STARband is intended for medical purposes for use on infants from 3 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 3 to 18 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 (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K124023