510(k) Summary

I. Applicant Information

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

Contact Information

Contact Person:	David Hooper, Manufacturing Engineer
Address:	6333 North Orange Blossom Trail Orlando, FL 32810
Telephone:	(407) 290-6592
Facsimile:	(407) 290-2419
Email:	dhooper@orthomerica.com
Date Prepared:	October 16, 2013

II. Submission Information

Type:	Traditional 510(k) Submission
Proprietary Name:	STARlight®
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

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IV. Description of Device/Modification

The STARlight redirects the head growth to improve proportion and symmetry. The practitioner takes a plaster impression or a scan of the infant'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 STARlight 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 further modified by the practitioner to provide space for growth to occur in the flat or depressed areas. The shape of the STARlight directs growth into the areas of least resistance and creates a precise pathway for the head shape to improve in symmetry and proportion.

The STARlight product family as it was released in K090587 are essentially still the same devices. The STARlight Side Opening design and the STARlight Bi-Valve design are made of a plastic shell of 5/32" – 1/4" clear Surlyn or 1/8" - 7/32" Clear Co-Polyester. The STARlight PRO (Post-operative Remolding Orthosis) design is made of 1/4" to 3/8" clear Surlyn. The STARband Bi-Valve design is made with an outer shell of 5/32" polyethylene-polypropylene copolymer plastic and an inner liner of 1/2" pelite polyethylene foam. Optional Aliplast (closed cell polyethylene) padding is available for the clear plastic bands and in addition optional Reston (polyurethane – 3M Medical Product) foam is available for the STARlight PRO design.

The STARlight Side Opening design has a top opening and a side opening. The band is held in place by a Velcro strap across the side opening. The STARlight PRO has two side openings, no top opening, and is held in place by a Velcro strap across each side opening. The STARlight Bi-Valve design and the STARband Bi-Valve design consist of two plastic shells that overlap with a superior sliding mechanism. The right and left overlap tabs are connected via a Velcro strap with chafe and loop.

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, either Class 1 or Class 2 depending on the option, and one camera to capture shape data. The Class 1 laser option of the scanGogh-II is as safe as other scanner devices previously cleared for the STARlight and will not require any extra safety precautions. The Class 2 laser option is safe to use on infant patients when used in conjunction with eye protection. The Class 1 laser option of the scanGogh-II shall be the recommended option for scanning infants. If the Class 2 option of the scanGogh-II is used, the infant should wear eye protection as instructed in the proposed labeling.

There have been changes made to the STARlight Side Opening and the STARlight PRO. The modifications involve the changing of the closure straps for the STARlight Side Opening and the STARlight PRO. The closure strap is a chafe and loop system similar to those used in the Bi-Valve designs. The STARlight Side Opening and the STARlight PRO also have the option of having a tamper resistant Velcro strap for the closure system. These were minor and determined to not require a 510(k) submission. Table 1 illustrates the minor differences between the cleared device (K090587) and the devices as it currently is marketed.

V. Statement of Indications and Intended Use

Statement of Indications:

The STARlight 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 STARlight 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 STARlight for approximately 23 hours per day. The most common head deformities are positional plagiocephaly, brachycephaly, and scaphocephaly. The STARlight 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

- STARlight, Cranial Orthosis, K090587
- STARband, Cranial Orthosis, K124023

VI. Summary of Technological Characteristics

The modification proposed is the use of an additional tool which can be used to capture the infant's head shape; the technological characteristics and the underlying principles of operation of the STARlight Cranial Orthosis will remain exactly the same. The other modifications include the removal of the STARlight Cap, the addition of a chafe buckle and an optional tamper resistant strap for the STARlight Side Opening and STARlight PRO designs. This table illustrates that the device will in fact remain the same.

Table 1 – Comparison of Predicate Device cleared in K090587 to the Proposed Device

Feature	From K090587	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	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 STARlight PRO - 1/4" – 3/8" clear Surlyn 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 top sliding mechanism - 1" Velcro strap - 1" chafe buckle - Speedy rivets Closure for STARlight Side Opening design and the STARlight PRO design: - 1" Velcro Strap (qty 2 for the STARlight PRO design)	Material for STARlight Side Opening and STARlight Bi-Valve - 5/32" - 1/4" clear Surlyn or 1/8" – 7/32" Clear Co-Polyester plastic shell Material for STARlight PRO - 1/4" – 3/8" clear Surlyn 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 top sliding mechanism - 1" Velcro strap - 1" chafe buckle - Speedy rivets Closure for STARlight Side Opening design and the STARlight PRO design: - 1" Velcro Strap - 1" chafe buckle - Optional tamper resistant strap (qty 2 for the STARlight PRO design)
Product Design	Custom made cranial orthosis, approximately 7 to 10oz in weight. STARlight PRO weighs 12.5 to 18.5 oz.	Custom made cranial orthosis, approximately 7 to 10oz in weight. STARlight PRO weighs 12.5 to 18.5 oz.

Feature	From K090587	Proposed Device
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 Material Biocompatibility Testing - Cytotoxicity –Agar Diffusion - Closed Patch Sensitization - Primary Dermal Irritation	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 Material Biocompatibility Testing - Cytotoxicity –Agar Diffusion - Closed Patch Sensitization - Primary Dermal Irritation

The inclusion of the scanGogh-II is the focus of this submission and that change is indicated in **Table 1** under the production section. 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 scanGogh-II has already received FDA clearance for the STARband Cranial Orthosis (K124023) which is also held by Orthomerica Products, Inc. The STARband and the STARlight are essentially the same device. They have the same indications for use and undergo the same manufacturing process. The main difference between the STARlight and the STARband are the materials used to produce them. The STARband and STARlight materials have been biocompatibility tested, and the results of the tests are listed below. Given that the technological characteristics of the STARband are the same as the proposed device, these devices are substantially equivalent.

Biocompatibility Test Results

Material	Test	Results	Conclusion
Surlyn	Closed Patch Sensitization	A score of 0.00/0.00 (Test/Control) was given for both Incidence and Severity in the 24 hour and 48 hour scoring interval.	Not a Sensitizer No Erythema or Edema Formation
Surlyn	Primary Dermal Irritation	Primary Irritation Index: 0.00	Negligible Dermal Response
Surlyn	Cytotoxicity – Agar Diffusion	Cell culture treated with test sample exhibited no reactivity (Grade 0).	Non-cytotoxic
Copolymer with Pelite Foam	Closed Patch Sensitization	A score of 0.00/0.00 (Test/Control) was given for both Incidence and Severity in the 24 hour and 48 hour scoring interval.	Not a Sensitizer No Erythema or Edema Formation
Copolymer with Pelite Foam	Primary Dermal Irritation	Primary Irritation Index: 0.06	Negligible Dermal Response
Copolymer with Pelite Foam	Cytotoxicity – Agar Diffusion	Cell culture treated with test sample exhibited no reactivity (Grade 0).	Non-cytotoxic
Copolymer with Aliplast Foam	Closed Patch Sensitization	A score of 0.00/0.00 (Test/Control) was given for both Incidence and Severity in the 24 hour and 48 hour scoring interval.	Not a Sensitizer No Erythema or Edema Formation

Copolymer with Aliplast Foam	Primary Dermal Irritation	Primary Irritation Index: 0.00	Negligible Dermal Response
Copolymer with Aliplast Foam	Cytotoxicity – Agar Diffusion	Cell culture treated with test sample exhibited slight reactivity (Grade 1).	Non-cytotoxic

VII. Summary and Conclusions of Non-Clinical Performance Data

The scanGogh-II was evaluated for safety and efficacy. The primary safety concern is the laser. The scanner uses either a Class 1 Laser or a Class 2 Laser. The Class 1 Laser version of the scanGogh-II is safe to use on infants without any extra protection. The Class 2 Laser version is safe as long as the patient has proper eye protection. An Eye Shield Fit Assessment was performed. The Eye Shield Fit Assessment showed the eye shields were an acceptable fit for infants as they completely covered the eye. Therefore, eye shields provide safe and effective protection of the infant's eye during scanning. 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. With sufficient accuracy and proper laser safety procedures, the scanGogh-II was determined safe and effective for scanning infants for STARlight 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 20993-0002

January 16, 2014

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

Re: K133250
Trade/Device Name: STARlight Cranial Orthosis
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: OAN, MVA
Dated: October 16, 2013
Received: October 22, 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 contact 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. 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 Carlos L. Peña, Ph.D., M.S.
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): K133250

Device Name: STARlight Cranial Orthosis

Indications For Use:

The STARlight 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 ✓ 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 Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S