DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 20, 2016

Orthomerica Products, Inc.
Mr. David L. Hooper
Manufacturing Engineer
6333 North Orange Blossom Trail
Orlando, Florida 32810

Re: K161138
Trade/Device Name St. Louis Band
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: MVA, OAN
Dated: April 20, 2016
Received: April 22, 2016

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161138

Device Name
St. Louis Band

Indications for Use *(Describe)*
The St. Louis Band 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. This 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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:	April 20th, 2016

II. Submission Information

Type:	Traditional 510(k) Submission
Proprietary Name:	St. Louis Band
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 St. Louis Band redirects the head growth to improve proportion and symmetry. The practitioner takes a plaster impression or 3-dimensional captured image of the infant's head to acquire the existing shape. The mold is sealed and filled with plaster or the 3-dimensional image 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 St. Louis Band provides total contact over the prominent or bossed areas of the baby's head to discourage growth there. Over the course of treatment, 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 St. Louis Band directs growth into the areas of least resistance and creates a precise pathway for the head shape to improve in symmetry and proportion.

The St. Louis Band (formally known as the O&P Bivalve Molding Helmet) was released in K063395. The St. Louis Band is a Bi-Valve design made with an outer shell of 1/4" polyethylene-polypropylene copolymer plastic with an inner liner made of 1/4" Aliplast foam (closed cell polyethylene). The Bi-Valve design consists of two plastic shells that overlap and are held together with rivet fasteners. The St. Louis Band utilizes a Velcro® strap with chafe and loop for a secure fit.

The proposed device modifications include:

(1) A clarification to the indications for use for the St. Louis Band. This change would have the device 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.

(2) The addition of two new 3-dimensional shape capture methods, specifically, the STARscanner™ Data Acquisition System and the SmartSoc™ System. The STARscanner is a stationary system that uses Class I Lasers and cameras to record surface data for shape capture. The SmartSoc System is a hand held system that uses a flexible fabric sock with a customized non-repetitive printed pattern and a consumer grade digital camera with it's a built-in flash light source. The built-in flash feature is a non-coherent (i.e. non-laser light) light source. Both of these shape capture systems are cleared with the STARband predicate device (K151979).

V. Statement of Indications and Intended Use

Statement of Indications:

The St. Louis Band 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. This 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 St. Louis Band is designed to treat infants with abnormal head shapes from age 3 to 18 months and is available by prescription only. Since growth is the driving factor in head shape correction, the infants wear the St. Louis Band for approximately 22 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 in 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 St. Louis Band is designed to maintain total contact over areas where growth is not desired and allow for space over areas where growth is desired. The St. Louis Band provides a pathway for the baby’s head growth, directing it toward a more normal shape.

VI. Predicate Devices

- STARband and STARlight, Cranial Orthosis, K151979
- O&P Bivalve Cranial Molding Helmet, Cranial Orthosis, K063395

VII. Summary of Technological Characteristics

The proposed changes involve the indications for use and the use of additional methods to capture the infant's head shape for the fabrication of St. Louis Band. The technological characteristics and the underlying principles of operation of the St. Louis Band Cranial Orthosis shall remain exactly the same. The inclusion of the STARscanner and SmartSoc System is indicated in **Table 1** under the Approved 3-Dimensional Imaging Devices section.

Table 1 – Comparison of Predicate Device cleared in K063385 to the Proposed Device

Feature	From K063395	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	O&P Bivalve Molding Helmet
	- Sliding/Overlap Closure System
	- Outer shell of 1/4" copolymer plastic
	- An inner liner of 1/4" Aliplast foam
	- Bi-Valve Closure
	  - Sliding/Overlap Closure System
	  - 1" Velcro strap
	  - 1" chafe buckle
	  - Speedy rivets
		St. Louis Band
		- Sliding/Overlap Closure System
		- Outer shell of 1/4" copolymer plastic
		- An inner liner of 1/4" Aliplast foam
		- Bi-Valve Closure
		  - Sliding/Overlap Closure System
		  - 1" Velcro strap
		  - 1" chafe buckle
		  - Speedy rivets

Product Design	Custom made cranial orthosis, approximately 7 to 10oz in weight.	Custom made cranial orthosis, approximately 7 to 10oz 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 from a traditional plaster cast	- Form orthosis from a positive mold of infant's head - Positive mold is formed based upon measurements of the infant's head taken by an approved 3-dimensional imaging device from which a 3-dimensional image is made or from a traditional plaster cast - The 3-dimensional image is used

Feature	From K063395	Proposed Device
		to produce a positive mold using a 5-axis routing machine
Approved 3-Dimensional Imaging Devices	- None	- STARscanner II - SmartSoc System
Testing	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 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 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 Material Biocompatibility Testing - Cytotoxicity –Agar Diffusion - Closed Patch Sensitization - Primary Dermal Irritation

Both the STARscanner and the SmartSoc System are cleared as an approved 3D imaging system for the predicate devices (STARband and STARlight) cleared under K151979. The St. Louis Band is substantially equivalent to these devices as they have the same intended use, underlying operating principles, and production processes. The St. Louis Band is specifically equivalent to the Bi-Valve design of the STARband as they are both a Bi-Valve design, consist of the same materials and have similar strapping mechanism. **Table 2** is a comparison of the STARband Bi-Valve cleared under K151979 and the proposed device.

Table 2 – Comparison of Predicate Device cleared in K151979 to the Proposed Device

Feature	From K151979 (STARband Bi-Valve Only)	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	STARband Bi-Valve
	- Outer shell of 5/32" copolymer plastic
	- An inner liner of 1/2" Pelite Polyethylene foam or 1/2" Aliplast foam
	- Bi-Valve Closure
	  - Sliding/Overlap Closure System
	  - Chicago Screw (or similar) for top sliding mechanism
	  - 1" Velcro strap
	  - 1" chafe buckle
	  - Speedy rivets
		St. Louis Band
		- Outer shell of 1/4" copolymer plastic
		- An inner liner of 1/4" Aliplast foam
		- Bi-Valve Closure
		  - Sliding/Overlap Closure System
		  - 1" Velcro strap
		  - 1" chafe buckle
		  - Speedy rivets

Product Design	Custom made cranial orthosis, approximately 7 to 10oz in weight.	Custom made cranial orthosis, approximately 7 to 10oz 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 an approved 3-dimensional imaging device 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 an approved 3-dimensional imaging device 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
Approved 3-Dimensional Imaging Devices	- STARscanner I - STARscanner II - Omega Scanner - scanGogh-II - 3dMDhead System - 3dMDcranial System - 3dMDflex System - SmartSoc System - M4DScan/BodyScan System - Spectra 3D Scanner	- STARscanner II - SmartSoc System

Since the physical design of the St. Louis Band is not changing and the proposed shape capture device's technological characteristics are exactly the same as those cleared for the predicate device (K151979: STARband and STARlight); the St. Louis Band Cranial Orthosis is substantially equivalent to the predicate device. **Table 3** below is a summary of the performance testing conducted on the STARscanner and the SmartSoc System and the results obtained when compared to the casting method.

Table 3 – Performance Testing Summary for Shape Capture Devices

Test	Test Method Summary	Results
Repeatability and Reproducibility (R&R) Analysis	The purpose of this test is to analyze the repeatability and reproducibility (components of precision) of the proposed shape capture devices. The data obtained is compared to the casting process. Utilized uniform shapes with known dimensions that represent various sizes of pediatric patients between ages 3 to 18 months of age. Associated test parameters include A-P and M-L.	The shape capture devices passed the acceptance criteria. The relevancy of the tests determined substantial equivalence of the proposed shape capture devices.
Cranial Shape Capture Accuracy Study	The purpose of this test is to analyze the accuracy of the proposed shape capture devices. The data obtained is compared to the casting process. Utilized a representative cranial shape that possesses a predefined shape with known dimensions. Associated parameters analyzed include A-P, M-L, P-D, various radius parameters, squareness, and flatness.	The shape capture devices passed the acceptance criteria for all parameters. The relevancy of the test determined substantial equivalence of the proposed shape capture device.

The St. Louis Band is essentially the same Cranial Orthosis as released in K063395. The St. Louis Band materials have been biocompatibility tested, and the results of the tests are listed below in **Table 4**.

Table 4 – Biocompatibility Testing Summary for St. Louis Band Cranial Orthosis

Material	Test	Results	Conclusion
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

VIII. Summary and Conclusions of Non-Clinical Performance Data

The St. Louis Band has been used successfully in clinical practice since its original clearance in 2006. The STARscanner and the SmartSoc System were evaluated for safety and efficacy. The primary safety issue for the STARscanner is the laser. The STARscanner is a Class I laser device and as such is inherently safe for use on infants without eye protection under all normal operating conditions. The SmartSoc System does not utilize lasers, but the flash feature from a consumer grade camera is used as a light source.

The shape capture repeatability and reproducibility for these systems were evaluated and determined to be acceptable. An additional, Cranial Shape Capture Accuracy Study was performed concluding that the STARscanner and SmartSoc System yield a product that is substantially equivalent to the predicate device. With sufficient accuracy and no concerns with the safety of the imaging devices, the STARscanner and SmartSoc System were determined to have a safety and effectiveness profile similar to the predicate device for capturing infant head shape data to manufacture the St. Louis Band Cranial Orthosis.