March 1, 2018

Orthomerica Products, Inc
J. Schulte
Design Engineer
6333 North Orange Blossom Trail
Orlando, Florida 32810

Re: K180109
Trade/Device Name: STARband, STARlight, and St. Louis Band
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: OAN, MVA
Dated: January 9, 2018
Received: January 16, 2018

Dear J. Schulte:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Hoffmann -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180109

Device Name
STARband®, STARlight®, and St. Louis Band

Indications for Use *(Describe)*
The STARband, STARlight, and St. Louis Band are 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. These devices are 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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K180109 510(k) Summary

I. Submitter Information

Name:	Orthomerica Products, Inc.
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Contact Information

Contact Person:	Tyler Schulte, Design Engineer
Email:	tschulte@orthomerica.com
Date Prepared:	March 1, 2018

II. Subject Device Information

Submission Type:	Special 510(k)
Proprietary Name:	STARband®, STARlight®, and St. Louis Band
Common Name:	Cranial Orthosis
Product Code:	OAN (Orthosis, Cranial, Laser Scan)
Secondary:	MVA (Cranial Orthosis)
Classification:	21 CFR 882.5970, Cranial Orthosis, Class II

III. Predicate Device

K151979	STARband, STARlight
Product Code	OAN, MVA
K161138	St. Louis Band
Product Code	OAN, MVA

IV. Description of Device Modification

The proposed device modification is the addition of the CurveCapture application for iOS enabled device for a previously cleared shape capture method, the NetVirta SmartSoc™ System distributed by Orthomerica Products, Inc, used with the STARband, STARlight, and St. Louis Band devices. The system uses a flexible fabric sock with a customized non-repetitive printed pattern and a consumer grade mobile phone device with a camera and a built-in flash light source. The built-in flash feature is a non-coherent (i.e. non-laser light) light source. Because the system utilizes a consumer grade camera with a non-coherent light source for a flash, it is safe to use on infant patients under all circumstances.

The proposed modification allows the CurveCapture™ application to be run on an iOS enabled device.

The CurveCapture™ application uses the camera on the device to take video footage of the patient wearing the SmartSoc. Specific images are then selected and sent to the cloud to be processed into a detailed 3D digital model of the patient's cranium. The proposed CurveCapture™ system for iOS enabled device functions the same way as the previously CurveCapture™ system for Android™ enabled devices.

The STARband® and STARlight® redirect head growth to improve proportion and symmetry in infants with moderate-to-severe non-synostotic positional plagiocephaly. The practitioner takes a plaster impression or 3-dimensional captured image the 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 STARband® and STARlight® provide 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 STARband® and 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 STARband® and STARlight® product families as it was cleared in K151979 and are fundamentally the same devices cleared in that 510(k). The STARband® Side Opening design and STARband® Bi-Valve design is made with an outer shell of 5/32" polyethylene-polypropylene copolymer plastic with an inner liner made of 1/2" pelite polyethylene foam or 1/2" Aliplast foam (closed cell polyethylene). The STARlight® Side Opening design and the STARligh®t 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. 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 STARband® Side Opening design and the STARlight® Side Opening design has a top opening and a side opening. The band is held in place by a Velcro® strap (1½" for STARband® Side Opening and 1" for STARlight® Side Opening) 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 St. Louis Band (formally known as the O&P Bivalve Molding Helmet) was first cleared in K063395 and later in K161138 and remains fundamentally the same device. 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.

V. Intended Use

The STARband®, STARlight®, and St. Louis Band are 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 devices are 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.

Since growth is the driving factor in head shape correction, the infants wear the STARband® or STARlight® for approximately 23 hours per day. The most common head deformities are positional plagiocephaly, brachycephaly, and scaphocephaly.[1] The STARband®, STARlight®, and St. Louis Band are also intended for unresolved head deformities in patients who have undergone surgery to correct craniosynostosis.[2] The same principles of cranial remolding apply to positional deformities and post-operative patients.

VII. Summary of Technological Characteristics

The iOS compatible CurveCapture™ application for the SmartSoc™ System proposed in this Special 510(k) is a firmware expansion of a previously cleared shape capture method used for the fabrication of the STARband®, STARlight®, and St. Louis Band Cranial Orthosis. The technological characteristics and the underlying principles of operation of the SmartSoc™ System, the STARband®, the STARlight®, and the St. Louis Band Cranial Orthosis shall remain exactly the same. The inclusion of the iOS compatible CurveCapture™ application is the focus of this submission and the resulting change is indicated in **Table 1** and **Table 2 below** within the feature section Approved 3-Dimensional Imaging Devices. The addition of the accuracy and capabilities study conducted on the iOS compatible CurveCapture™ application is also indicated in the Accuracy Verification section of the Design Controls Summary.

[1] For a discussion of positional plagiocephaly and brachycephaly, please reference the OPI Band 510(k) Summary for K001167, and the STARlight 510(k) Summary for K021207

[2] For a discussion on Cranial Remolding after Corrective Craniosynostosis surgery, please reference the STARband 510(k) Summary for K082950 and the STARlight 510(k) Summary for K081994

Table 1 – Comparison of Predicate Device cleared in K151979 to the Subject Device

Feature	Predicate K151979	K180109
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 STARband® Side Opening design and STARband® Bi-Valve design - Outer shell of 5/32" copolymer plastic - An inner liner of 1/2" Pelite polyethylene foam or 1/2" Aliplast foam Material for STARlight® Side Opening design and STARlight® Bi-Valve design - 5/32" - 1/4" clear Surlyn or 1/8" – 7/32" Clear Co-Polyester plastic shell Material for STARlight® PRO design - 1/4" – 3/8" clear Surlyn 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 STARband® Side Opening design - 1 ½" Velcro Strap - 1 ½" chafe buckle - A Gap Block made from ½" firm Pelite polyethylene foam - Large Flange, Blind Rivet Closure for STARlight® Side Opening design and the STARlight® PRO design:	Material for STARband® Side Opening design and STARband® Bi-Valve design - Outer shell of 5/32" copolymer plastic - An inner liner of 1/2" Pelite polyethylene foam or 1/2" Aliplast foam Material for STARlight® Side Opening design and STARlight® Bi-Valve design - 5/32" - 1/4" clear Surlyn or 1/8" – 7/32" Clear Co-Polyester plastic shell Material for STARlight® PRO design - 1/4" – 3/8" clear Surlyn 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 STARband® Side Opening design - 1 ½" Velcro Strap - 1 ½" chafe buckle - A Gap Block made from ½" firm Pelite polyethylene foam - Large Flange, Blind Rivet Closure for STARlight® Side Opening design and the STARlight® PRO design:

Feature	Predicate K151979	K180109
	- 1” Velcro Strap - 1” chafe buckle Optional tamper resistant strap (qty 2 for 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 6 to 10oz in weight. STARlight® PRO weighs 12.5 to 18.5 oz.	Custom made cranial orthosis, approximately 6 to 10oz in weight. STARlight® PRO weighs 12.5 to 18.5 oz.
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 - M4DScan/BodyScan System - Spectra 3D Scanner - SmartSoc System for Android Device	- STARscanner I - STARscanner II - Omega Scanner - scanGogh-II - 3dMDhead System - 3dMDcranial System - 3dMDflex System - M4DScan/BodyScan System - Spectra 3D Scanner - SmartSoc System for Android Device - SmartSoc System for iOS Device
SmartSoc System Mobile Device Characteristics	Image Sensor - 10.0 Mega Pixels Lens focal length - F=24 mm (minimum) Focusing - Auto- Focus (Center AF, Multi AF, Face Detection AF) Shooting - Still images automatic - Video automatic Image Stabilization - Optical Image Stabilization Capability	Image Sensor - 10.0 Mega Pixels Lens focal length - F=24 mm (minimum) Focusing - Auto- Focus (Center AF, Multi AF, Face Detection AF) Shooting - Still images automatic - Video automatic Image Stabilization - Optical Image Stabilization Capability

Feature	Predicate K151979	K180109
	Storage - 4 Gb Total (minimum) - 1 Gb (minimum) for normal utilization Wireless Connectivity - Wi-Fi, 3G, 4G - HTML Browser - WAP Browser CPU/Processor - 1.04 GHz or faster Operating System - Android 2.3.3 or Newer	Storage - 4 Gb Total (minimum) - 1 Gb (minimum) for normal utilization Wireless Connectivity - Wi-Fi, 3G, 4G - HTML Browser - WAP Browser CPU/Processor - 1.04 GHz or faster Operating System - Android 2.3.3 or Newer - iOS 10.3 or Newer
Testing	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	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

Since the St. Louis Band relies on the same materials and fundamental technology and has the same intended use as the STARband® and STARlight® Cranial Orthosis, it is substantially equivalent to the device cleared in K151979. However, when the St. Louis Band was cleared in K161138, it was approved to use the STARscannerII and the SmartSoc System for Android Device as 3D imaging devices. The proposed change would only add the SmartSoc System for iOS device as an approved 3D imaging device as shown in **Table 2**, not all the approved 3D imaging devices used for STARband® and STARlight® shown above in **Table 1**.

Table 2 – Comparison of Predicate Device cleared in K161138 to the Subject Device

Feature	Predicate K161138	K180109
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	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
		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 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 II - SmartSoc System for Android Device	- STARscanner II - SmartSoc System for Android Device - SmartSoc System for iOS Device
SmartSoc System Mobile Device Characteristics	Image Sensor - 10.0 Mega Pixels Lens focal length - F=24 mm (minimum) Focusing - Auto- Focus (Center AF, Multi AF, Face Detection AF) Shooting - Still images automatic - Video automatic Image Stabilization	Image Sensor - 10.0 Mega Pixels Lens focal length - F=24 mm (minimum) Focusing - Auto- Focus (Center AF, Multi AF, Face Detection AF) Shooting - Still images automatic - Video automatic Image Stabilization

Feature	Predicate K161138	K180109
	- Optical Image Stabilization Capability Storage - 4 Gb Total (minimum) - 1 Gb (minimum) for normal utilization Wireless Connectivity - Wi-Fi, 3G, 4G - HTML Browser - WAP Browser CPU/Processor - 1.04 GHz or faster Operating System - Android 2.3.3 or Newer	- Optical Image Stabilization Capability Storage - 4 Gb Total (minimum) - 1 Gb (minimum) for normal utilization Wireless Connectivity - Wi-Fi, 3G, 4G - HTML Browser - WAP Browser CPU/Processor - 1.04 GHz or faster Operating System - Android 2.3.3 or Newer - iOS 10.3 or Newer
Testing	Material Biocompatibility Testing - Cytotoxicity –Agar Diffusion - Closed Patch Sensitization - Primary Dermal Irritation	Material Biocompatibility Testing - Cytotoxicity –Agar Diffusion - Closed Patch Sensitization - Primary Dermal Irritation

The STARband® and STARlight® Cranial Orthosis and the St. Louis Band Cranial Orthosis have already received FDA 510(k) clearance under K151979 and K161138 respectively to be manufactured from a 3-dimensional image captured using the SmartSoc™ System for android enabled devices. The expansion of the SmartSoc™ System to include a CurveCapture application iOS enabled devices does not alter any of the fundamental technological principals of the SmartSoc™ System. Considering that STARband®, STARlight®, and St. Louis Band are still the same device as it was in the predicate device and that the shape capture devices have the same technological characteristics; the STARband®, STARlight®, and St. Louis Band Cranial Othosis are substantially equivalent to the predicate device.

The STARband®, STARlight®, and St. Louis Band are essentially the same Cranial Orthosis. The main difference between the STARband®, STARlight®, and St. Louis Band are the materials used to produce them. The STARband®, STARlight®, and St. Louis Band materials have demonstrated biocompatibility through testing, and the results of the tests are listed below in **Table 3 below**.

Table 3 – Biocompatibility Testing Summary for STARband, STARlight, and St. Louis Band Cranial Orthosis

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 SmartSoc™ System for iOS device was evaluated for safety and efficacy. The system uses a consumer grade camera and is safe to use on infants without any eye protection. Cranial Shape Capture Accuracy Verification was performed concluding that the SmartSoc™ System for iOS enabled device yields a safe and effective product that is substantially equivalent to the predicate device. With sufficient accuracy and no concerns with the safety of the system, the SmartSoc™ System for iOS enabled device was determined safe and effective for capturing infant head shape data to manufacture the STARband®, STARlight®, and St. Louis Band Cranial Orthosis.