August 17, 2021

Orthomerica Products, Inc.
Najiba Katir
Regulatory Compliance Manager
6333 North Orange Blossom Trail
Orlando, Florida 32810

Re: K211376
Trade/Device Name: STARband
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: OAN, MVA
Dated: July 2, 2021
Received: July 6, 2021

Dear Najiba Katir:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211376

Device Name
STARband

Indications for Use *(Describe)*
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 will 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
K211376

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:	Najiba Katir, Regulatory Compliance Manager
Address:	6333 North Orange Blossom Trail Orlando, FL 32810
Telephone:	(407) 290-6592
Facsimile:	(407) 290-2419
Email:	nkatirr@orthomerica.com
Date Prepared:	August 12th, 2021

II. Submission Information

Type:	Special 510(k) Submission
Proprietary Name:	STARband®
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 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 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 further modified 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® Side Opening design and STARband® Bi-Valve design are 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 STARband® 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) across the side opening. The STARband® Bi-Valve design consists 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 STARband® Plus cranial orthosis device proposed in this submission has identical indications for use to the predicate submission K082950. The difference with this proposed device is a structural change to a dual side opening design with a living hinge at the top. The indications for use, the intended use, and the underlying principles of operation of the STARband® cranial orthosis remain exactly the same.

V. Indications for Use and Intended Use

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 will 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 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 Device

- STARband® Cranial Orthosis – K082950

VII. Summary of Technological Characteristics

The STARband® Plus cranial orthosis device proposed in this submission has identical indications for use to the predicate submission K082950. The difference with this proposed device is a structural change to a dual side opening design with a living hinge at the top. The indications for use, the intended use, and the underlying principles of operation of the STARband® cranial orthosis remain exactly the same. The following **Table 1** clearly illustrates the similarities and differences between the two submissions.

Note that several submissions occurred between the proposed submission and the time the predicate device was cleared. This explains some additions in the right column compared to the predicate device; additions which were cleared, remain unchanged and are not impacted by the proposed submission (e.g., Approved 3-Dimensional Imaging Devices and approximate weight of the STARlight PRO).

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

Feature	From K082950	K211376
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.
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-	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-

Feature	From K082950	K211376
	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 will have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.	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 will have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.
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 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:	Material for STARband® Side Opening design, STARband® Bi-Valve design, and STARband® Plus 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 STARband® Plus design - (2) 1" Velcro Strap - (2) 1" chafe buckle - Large Flange, Blind Rivet Closure for STARlight® Side Opening design and the STARlight® PRO design:

Feature	From K082950	K211376
	- 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 Weight	Custom made cranial orthosis, approximately 6 to 10oz in weight.	STARband (Subject Device) weighs approximately 6 to 10oz. STARlight® PRO (cleared after K082950) weighs approximately 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 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 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	- 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
Testing	Material Biocompatibility Testing - Cytotoxicity –Agar Diffusion - Closed Patch Sensitization - Primary Dermal Irritation	Material Biocompatibility Testing - Cytotoxicity - Sensitization - Irritation

The STARband® Plus has the same intended use, indications, materials, basic design, and production as the predicate STARband® device in K082950. Therefore the STARband® Plus proposed in this submission is substantially equivalent to the previously cleared predicate device.

Table 2 – Biocompatibility Testing Summary for STARband® Cranial Orthosis

Material	Test	Results	Conclusion
Adhesive with AliPlast Foam	Sensitization – Kligman Maximization	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
Adhesive with AliPlast Foam	Irritation – Primary Dermal	Primary Irritation Index: 0.00	Negligible Dermal Response
Adhesive with AliPlast Foam	Cytotoxicity – MEM Elution	Cell culture treated with test sample exhibited no reactivity (Grade 0).	Non-cytotoxic
Copolymer with Pelite Foam	Sensitization – Closed Patch	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	Irritation – Primary Dermal	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	Sensitization – Closed Patch	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	Irritation – Primary Dermal	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 of Non-Clinical Performance Data

For the STARband Plus non-clinical performance test, it is assumed the cranial remolding orthosis is donned and doffed roughly 4 times a day for 6 months. The goal is to introduce localized fatigue at the living hinge by applying a repeated stress for 1440 cycles. Once the part has achieved 1440 cycles or fatigue life, whichever is reached first, the helmet will be removed from the machine/fixture and all materials located at the hinge (both plastic and foam), will be visually assessed for signs of wear or failure (fracture or yield). The success criteria for this test is determined by the living hinge achieving, or exceeding, 1440 cycles without experiencing failure.

All STARband Plus configurations (1/2" Aliplast, (4) 1/8" Aliplast, and ½" Pelite) successfully completed 1440 cycles without fatigue/failure impacting the living hinge. The sample population included both deformational and post-operative patients. STARband Plus living hinge design exceeded the normal application life cycle. The helmet durability across all liner types is verified at confidence level to structurally withstand the donning/doffing process throughout a 6-month treatment.

IX. Conclusion

The STARband® Plus cranial orthosis device proposed in this submission is substantially equivalent given that it has the same indications for use, intended use, and underlying principles of operation to the predicate submission K082950.