April 20, 2023

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

Re: K223238
Trade/Device Name: STARband 3D
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: MVA, OAN
Dated: March 20, 2023
Received: March 21, 2023

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 -S
Digitally signed by Adam D. Pierce -S
Date: 2023.04.20 14:31:57 -04'00'

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

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)*
K223238

Device Name
STARband 3D

Indications for Use *(Describe)*
The STARband 3D 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.

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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K223238 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:	Najiba Katir, Regulatory Compliance Manager
Address:	6333 North Orange Blossom Trail Orlando, FL 32810
Telephone:	(407) 290-6592
Facsimile:	(407) 290-2419
Email:	nkatir@orthomerica.com
Date Prepared:	March 20th, 2023

II. Submission Information

Submission Number:	K223238
Type:	Traditional 510(k) Submission
Proprietary Name:	STARband 3D
Classification:	Class II (special controls); OAN; MVA; 21 CFR 882.5970
Classification Name:	Cranial Orthosis
Predicate Device:	K211376

III. Manufacturing Site 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

IV. Description of Device/Modification

The STARband® redirects the head growth to improve proportion and symmetry. The practitioner takes a 3-dimensional captured image of the infant's head to acquire the existing shape. The 3-dimensional 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 following designs are identical to the predicate and have underdone no changes since the predicate clearance:
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 device consists of a dual side opening low profile design with a one-piece living hinge at the top and multiple liner options.

The following design is the Subject Device:
The STARband® 3D™ cranial orthosis device proposed in this submission has identical indications for use to the predicate submission K211376. The difference with this proposed device is a structural change with a bilateral side opening design and two latch closure mechanisms at each opening. The indications for use, the intended use, and the underlying principles of operation of the STARband® cranial orthosis remain the same.

V. Indications and Intended Use

Indications:

The STARband 3D 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.

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 same principles of cranial remolding apply to positional deformities.

VI. Predicate Device and Reference Device

- Predicate Device: STARband® Cranial Orthosis – K211376
- Reference Device: MyCRO Band – K201426

VII. Summary of Technological Characteristics

The STARband® 3D™ cranial orthosis device proposed in this submission has the same indications for use, intended use, underlying principles of operations and basic design as the predicate device as illustrated in **Table 1** below.

Table 1 – Comparison of Proposed Device, Predicate Device, and Reference Device

Device Characteristic	**Proposed Device**	**Predicate Device K211376**	**Reference Device K201426**
Manufacturer	Orthomerica Products, Inc.	Orthomerica Products, Inc.	Otto Bock HealthCare LP
Product Code	OAN, MVA	OAN, MVA	OAN, MVA
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.	Redirects head growth by maintaining contact over cranial areas which protrude and by creating voids over areas of depression or flattening in order to improve symmetry.
Contraindications	Not for use on infants with synostosis or hydrocephalus	Not for use on infants with synostosis or hydrocephalus	Not for use on infants with pre-surgical craniosynostosis or hydrocephalus
Prescription required?	Prescription Use Only	Prescription Use Only	Prescription Use Only
Size Options	Patient-matched sizing by scanning an image of patient's head shape	Patient-matched sizing by scanning an image of patient's head shape or	Patient-matched sizing by scanning an image of patient's head shape

Device Characteristic	Proposed Device	Predicate Device K211376	Reference Device K201426
		plaster mold to make positive mold of head shape	
Software Used for Shape	CAD software is used to modify the shape of the scanned image to improve symmetry and shape of the helmet to be manufactured	Customized and/or CAD software may be used to modify the shape of the scanned image to improve symmetry and shape of the helmet to be manufactured	CAD software is used to modify the shape of the scanned image to improve symmetry and shape of the helmet to be manufactured
Design Components	Polymer helmet with bi-lateral side-opening, closures, and zone padded lining	Polymer helmet with side opening closure and padded lining	Polymer helmet with side opening closure and padded lining
Approximate Device Weight	4 – 6.5 oz	6 – 10 oz	4 – 6.5 oz
Manufacturing Process	Additively manufactured orthosis based upon measurements of the infant's head captured by a previously cleared 3-dimensional imaging device	- 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	Additively manufacture the orthosis based upon measurements of the infant's head taken by a compatible 3-dimensional imaging device
Approved 3-Dimensional Imaging Devices	STARscanner I STARscanner II	Spectra 3D Scanner M4DScan/BodyScan System Omega Scanner 3dMDhead System 3dMDcranial System 3dMDflex System scanGogh-II STARscanner I STARscanner II SmartSoc System for Android and iOS devices	Creaform HCP Creaform Peel1 Creaform Peel 3D Rodin4D M4D Scan TechMed3D BodyScan OMEGA Scanner 3D Artec Eva Artec Eva Lite iFab EasyScan

Device Characteristic	Proposed Device	Predicate Device K211376	Reference Device K201426
Testing	Test samples were additively manufactured from 3D images of representative cranial shapes using previous cleared scanning device(s). Process Validation included Dimensional Analysis, Fit Assessment and Mechanical Testing of test samples to evaluate the additive manufacturing process performance, which was compared to the process used for the predicate device.	Cranial Shape Capture Accuracy Study utilized a representative cranial shape that possesses a predefined shape with known dimensions, which compared proposed device to cast and predicate device. Associated parameters analyzed included coordinate planes (A-P; M-L; P-D) and various radius parameters, squareness, and flatness.	Scanner Evaluation utilized a worst-case challenge reference object of known dimensions to assess 3D imaging devices for adequate accuracy, repeatability, and reproducibility. Scanners were compared to those previously cleared for use for the predicate device as well as internal acceptance criteria. Software Validation demonstrated software performance, interoperability, and ability to meet internal device specifications. In addition to IQ, OQ, and PQ studies, a Fit Assessment was performed using test samples which were additively manufactured from 3D images of representative simulated cranial shapes using a compatible scanner. Process Validation included dimensional analysis and mechanical testing of test samples to evaluate the additive manufacturing process performance, which was compared to the process used for the predicate device.
Biocompatibility	Material Biocompatibility Testing • Cytotoxicity • Sensitization • Irritation	Material Biocompatibility Testing • Cytotoxicity • Sensitization • Irritation	Material Biocompatibility Testing • Cytotoxicity • Sensitization • Irritation

VIII. Summary and Conclusion of Non-Clinical Performance Data

Test Type	Test Name	Test Method Summary	Test Results
Dimensional Analysis	Dimensional Analysis	Dimensional analysis was performed by manually overlaying the 3D-printed part scan file on the original design file using Autodesk Netfabb Premium Software. Dimensional differences were recorded at assigned locations to analyze the dimensional variability between 3D printed parts and computer design files.	Dimensional analysis of the additively manufactured Starband® 3D orthoses resulted in acceptable part consistency and reproducibility across build cycles for both controlled and random sample population.
Fit Analysis	Fit Assessment	The fit assessment was performed using 3/16" pads that were installed in the additively manufactured samples which were fit to the unmodified patient matched mold and visually assessed for proper fit, form and function	The fit assessment of the additively manufactured Starband® 3D orthoses was successful for all parts evaluated. All helmets aligned and secured properly and total contact (appropriate hold) was achieved at the prominent or bossed areas of the unmodified patient model.
	Pressure Test	The pressure test was performed by placing force sensors at the holding areas (dependent on diagnosis and pad configuration) at the patient-helmet interface and then pressure force was recorded. Results of this test are aimed to prove that pressure distribution for the Starband 3D design, when fit on patient, is equivalent to or better than the predicate device.	The Starband® 3D orthoses design successfully showed that the pressure force is comparable to the predicate device.
Mechanical Analysis	Latch Closure Cyclic Test	The latch closure cyclic test consisted of introducing localized fatigue at the latch closure by applying repeated stress for a specific amount of cycles. Pull forces to disengage (open) the latch closure where obtained before starting the cycle testing and then every predetermined amount of cycles.	The latch closure design successfully exceeded the established don & doff cycles without fatigue or failure impacting function during normal utilization. The design maintained operational criteria of latching and successfully securing the anterior and posterior shells on the patient model throughout the duration of the cyclic fatigue

			testing.
	Latch Closure Destructive Testing	Latch closure samples were affixed to the testing machine and a linear pull-force (perpendicular to the helmet's exterior surface) was applied to the latch until failure occurred. The maximum force required to fail the latch must exceed a maximum average pull strength of 9.18 lbf for and adult using defined pinch grips (Razza et al., 2022)	Destructive testing successfully proved that the STARband 3D latch closure design exceeds the average pull strength of an adult when using various pinch grips in application. It was concluded that the latch closure mechanism can withstand and surpass the pull forces of Don & Doff throughout the entire treatment.
Biocompatibility Analysis	Material Biocompatibility Test	Biological evaluation tests were performed to verify conformance of the materials used in the STARband 3D device in accordance with the ISO 10993-5 and ISO 10993-10 standards. Biocompatibility testing involved irritation, cytotoxicity and sensitization testing on the finished, fully assembled additively manufactured device.	Biocompatibility test reports demonstrate that all biocompatibility testing successfully met the acceptance criteria.

The above Non-Clinical Performance test results demonstrate that the proposed device performs and is as safe and effective as the predicate device and support the determination of substantial equivalence between the proposed device and the predicate device.

IX. Conclusion on Substantial Equivalence

The STARband® 3D™ cranial orthosis device proposed in this submission is substantially equivalent to the predicate device in K211376, given that it has the same indications for use, intended use, and underlying principles of operation and that non-clinical performance test results support that determination.