March 15, 2024

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

Re: K240466
Trade/Device Name: STARband 3D
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: OAN, MVA
Dated: February 16, 2024
Received: February 16, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 2024.03.15 09:19:21 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
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and Physical Medicine Devices
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240466

Device Name

STARband 3D

Indications for Use *(Describe)*

The STARband® 3D™ 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 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.

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 13th, 2024

II. Device Information

Proprietary Name:	STARband® 3D™
Classification:	Class II (special controls); OAN; MVA; 21 CFR 882.5970
Classification Name:	Cranial Orthosis

VI. Legally Marketed Predicate Device and Reference Device

- Predicate Device: STARband® 3D™ Cranial Orthosis – K223238
- Reference Device: STARband® Cranial Orthosis – K211376

IV. Device Description/Modification Summary

The STARband® 3D™ 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® 3D™ 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® 3D™ directs growth into the areas of least resistance and creates a precise pathway for the head shape to improve in symmetry and proportion.

Proposed Modification:
The STARband® 3D™ cranial orthosis device proposed in this submission has identical indications for use to the predicate submission K223238. The difference with this proposed device is the addition of scanning technologies which were already cleared by Orthomerica Products Inc. for use with its reference device K211376 and have undergone no change since the reference device clearance.

The indications for use, the intended use, and the underlying principles of operation of the STARband® 3D™ cranial orthosis remain the same.

V. Indications for Use and Intended Use

Indications for Use:

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® 3D™ 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® 3D™ 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.

Indications for Use Comparison
The indications for use of the proposed device are identical to the ones of the predicate device and the reference device.

VII. Summary of Technological Characteristics Comparison

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 Subject Device, Predicate Device, and Reference Device.

Device Characteristic	**Subject Device**	**Predicate Device K223238**	**Reference Device K211376**
Manufacturer	Orthomerica Products, Inc.	Orthomerica Products, Inc.	Orthomerica Products, Inc.
Trade Name	STARband 3D	STARband 3D	STARband
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.	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.
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 synostosis 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	Patient-matched sizing by scanning an image of patient's head shape or 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	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
Design Components	Polymer helmet with bi-lateral side-opening, closures, and zone padded lining	Polymer helmet with bi-lateral side-opening, closures, and zone padded lining	Polymer helmet with side opening closure and padded lining
Approximate Device Weight	4 – 6.5 oz	4 – 6.5 oz	6 – 10 oz

Device Characteristic	Subject Device	Predicate Device K223238	Reference Device K211376
Manufacturing Process	Additively manufactured orthosis based upon measurements of the infant's head captured by previously cleared 3-dimensional imaging devices	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
Approved 3-Dimensional Imaging Devices	STARscanner I STARscanner II Spectra 3D Scanner M4DScan/BodyScan System 3dMDhead System 3dMDcranial System 3dMDflex System SmartSoc System for Android and iOS 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
Testing	Nonclinical performance testing performed for the predicate device and reference device remains applicable as there was no design change to the device. Validation was conducted to evaluate one potential risk identified during design control activities and no impact on safety or effectiveness was identified. These tests are referenced in the submittion	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.
Biocompatibility Same as predicate	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

Non-Clinical Performance tests conducted for the predicate and reference devices, and referenced in this submission, passed all verification and validation acceptance criteria and demonstrated their safety and effectiveness. Given that the change proposed for the subject device requires no additional performance testing, these tests remain valid for the subject device, and they 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 K223238, given that it has the same indications for use, intended use, and underlying principles of operation and that previous non-clinical performance test results support that determination.