June 9, 2022

Otto Bock Healthcare LP
% Adrienne Von Foller
Regulatory Consulant
Strategic Quality Solutions, LLC
1594 E. Monaco Ave
Salt Lake City, Utah 84121

Re: K213587
Trade/Device Name: MyCRO Band
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: MVA, OAN
Dated: May 11, 2022
Received: May 13, 2022

Dear Adrienne Von Foller:

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 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)*
K213587

Device Name
MyCRO Band

Indications for Use *(Describe)*
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 an 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.

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

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510(k) Summary

Name of 510(k) Owner:	Otto Bock HealthCare LP
Address of Submitter:	3820 West Great Lakes Drive Salt Lake City, UT 84120 Telephone: (801) 956-2400
Submitter Contact:	Caleb Beck, Director, Regulatory and Quality Compliance – North America Adrienne von Foller Regulatory Affairs Consultant Strategic Quality Solutions, LLC Telephone: (801) 916-8188 Email: Adrienne@device2market.com
Date Prepared:	June 9, 2022
Submission Type:	Traditional 510(k)
Proprietary Name:	MyCRO Band
Common Name(s):	Cranial orthosis
Classification:	21 CFR 882.5970, Cranial orthosis
Device Class:	Class II
Device Product Code:	MVA, OAN
Predicate Device:	K180109 – Orthoamerica Products, Inc., STARband®
Reference Device:	K201426 – Otto Bock HealthCare LP, MyCRO Band

Device Description

The Ottobock MyCRO Band is a non-sterile temporary orthosis to aid in the correction of head shape caused by positioning in infants three (3) to eighteen (18) months of age. As such, this device is manufactured to match patient anatomy and may only be used on the patient for which the cranial orthosis was designed. The orthosis uses contact and growth zones to guide the growth of the head. The contact zones define limits for growth, while the growth zones leave space in areas required for forming the natural head shape. An adaptable closure allows for adjustability as the child grows. The orthosis is made of thermoplastic material with a soft, washable lining on the interior.

Indications for Use

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 an 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.

Basis for Substantial Equivalence

The Ottobock MyCRO Band has the following technological characteristics which are the same as the predicate device. These include:

1. Indications for use
2. Intended use
3. Basic principles of operation
4. Basic design

Comparison of the Subject and Predicate Devices			
Device Characteristic	**Subject Device**	**Reference Device**	**Predicate Device**
Trade Name Common Name	MyCRO Band Cranial Helmet, Cranial Orthosis		STARband Cranial Helmet, Cranial Orthosis
Manufacturer	Otto Bock HealthCare LP		Orthomerica Products, Inc.
510(k) Number	K213587	K201426	K180109
Product Code	MVA, OAN	MVA	OAN, MVA
Intended Use	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.		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 pre-surgical craniosynostosis or hydrocephalus		Not for use on infants with synostosis or hydrocephalus
Prescription required?	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 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
Design Components	Polymer helmet with side opening closure and padded lining		Polymer helmet with side opening closure and padded lining
Approximate Weight	4 – 6.5 oz		6 – 10 oz

Comparison of the Subject and Predicate Devices			
Device Characteristic	**Subject Device**	**Reference Device**	**Predicate Device**
Manufacturing Process	Additively manufacture the orthosis based upon measurements of the infant's head taken by a compatible 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
Compatible 3-Dimensional Imaging Devices	Creaform HCP Creaform Peel1 Creaform Peel 3D Rodin4D M4D Scan TechMed3D BodyScan OMEGA Scanner 3D Artec Eva Artec Eva Lite iFab EasyScan	Creaform HCP Creaform Peel1 Creaform Peel 3D Rodin4D M4D Scan TechMed3D BodyScan OMEGA Scanner 3D Artec Eva Artec Eva Lite	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	Scanner Evaluation utilized a worst-case challenge reference object of known dimensions to assess 3D imaging devices for adequate accuracy, repeatability, and reproducibility. The iFab EasyScan was compared to scanners previously cleared for use as well as internal acceptance criteria. Verification testing demonstrated software performance, interoperability, and ability to meet internal device specifications. Verification testing included dimensional analysis, fit assessment, and mechanical testing of test samples to evaluate the iFab EasyScan as part of the manufacturing process performance, which was compared to the process used for the predicate device.	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	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.

Comparison of the Subject and Predicate Devices			
Device Characteristic	**Subject Device**	**Reference Device**	**Predicate Device**
		samples to evaluate the additive manufacturing process performance, which was compared to the process used for the predicate device.	
Biocompatibility	Biocompatibility Testing • Cytotoxicity • Sensitization • Irritation		Biocompatibility Testing • Cytotoxicity • Sensitization • Irritation

In addition, the subject device complies with the special controls for cranial orthoses under 21 CFR 882.5970 for the FDA product classification, including labeling and biocompatibility test requirements.

Summary of Testing

The following non-clinical tests were conducted and successfully met the predetermined acceptance criteria:

1. Biological evaluation per ISO 10993-1:2018
2. Cytotoxicity testing per ISO 10993-5:2009
3. Irritation and Sensitization testing per ISO 10993-10:2010
4. Scanner evaluation, including repeatability/reproducibility study
5. Verification testing

Conclusion

The MyCRO Band has identical indications for use as the predicate device in K180109. The fundamental technological characteristics of the MyCRO Band are the same as the previously cleared predicate device. All testing passed acceptance criteria and demonstrated that the subject device is substantially equivalent to the predicate device.

Based on similarities in indications for use, basic design, and the principle of operation, the Ottobock MyCRO Band is substantially equivalent to the previously cleared predicate device.