July 1, 2022

Symbion Logistics, LLC
Roselle Abad
Quality Engineer
1119 W Geneva Dr
Tempe, Arizona 85281

Re: K203134
Trade/Device Name: Hanger Cranial Band 3D
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: MVA, OAN
Dated: September 30, 2021
Received: October 4, 2021

Dear Roselle Abad:

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)*
K203134

Device Name
HANGER CRANIAL BAND 3D

Indications for Use *(Describe)*
Intended for medical purposes to apply static or gentle pressure to prominent regions of an infant's cranium to improve cranial symmetry or shape. To treat infants from three to eighteen months of age with moderate to severe non-synostotic positional plagiocephaly, including plagiocephalic-, brachycephalic-, scaphocephalic-shaped heads.

Contraindications for use: Infants with synostosis or hydrocephalus.

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
K203134

I. Application Information

A. Applicant Name and Address

Symbiont Logistics, LLC (dba Hanger Fabrication Network)
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Phoenix, AZ 85042
T: 480-894-1755 F: 480-921-9686

FDA Establishment Registration Number: 2032381

B. Submission Correspondent

Roselle Abad
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C. Contact Person

Antonio Dias
Engineering Director, Hanger Fabrication Network (Symbiont Logistics, LLC)
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D. Summary Date – June 27, 2022

II. Submission Information

A. Trade or Proprietary Name:	Hanger Cranial Band 3D
B. Common Name:	Cranial Orthosis, Helmet
C. Regulation Classification:	Orthosis, Cranial, Laser Scan
D. Regulation Number:	882.5970
E. Product Code:	MVA, OAN
F. Panel:	Neurology
G. Device Class:	II
H. Predicate Device 510(k):	Hanger Cranial Band, K072566

III. Device Description

The Hanger Cranial Band 3D is a cranial remolding orthosis comprised of an additive-manufactured outer shell with a polyethylene foam inner lining.

The device is custom fabricated for individual patients by obtaining measurements via a handheld 3D laser scanner. Clinical measurements of the infant's cranium are taken from the digital file. The scan is then modified utilizing a CAD/CAM technology package—to add or remove material, increase or decrease the circumference of model to aid in fit and

functionality of the cranial orthosis. The 3D image is used to produce a positive mold using a routing machine, to which the foam liner is pulled onto. The 3D file is also used manufacture the outer shell, which is then attached to the foam-lined positive model.

The completed device applies gentle pressure to the elevated areas of the skull while leaving space for cranial growth in the depressed regions. It is open at one side and closed with a fastener to provide the selected fit and proper stability.

IV. Indication for Use Statement

Intended for medical purposes to apply static or gentle pressure to prominent regions of an infant's cranium to improve cranial symmetry or shape. To treat infants from three to eighteen months of age with moderate to severe non-synostotic positional plagiocephaly, including plagiocephalic-, brachycephalic-, scaphocephalic-shaped heads.

Contraindications for use: Infants with synostosis or hydrocephalus.

V. Substantial Equivalence Discussion

The comparison chart below provides evidence to facilitate the substantial equivalence determination between Hanger Cranial Band 3D to the predicate device, Hanger Cranial Band (K0272566) with respect to intended use, technological characteristics and principles of operation.

Table 1 – Comparison of Characteristics

Features	Predicate Device Hanger Cranial Band, K072566	Proposed Device Hanger Cranial Band 3D
Intended Use/ Indications for Use	Intended for medical purposes to apply static or gentle pressure to prominent regions of an infant's cranium to improve cranial symmetry or shape. To treat infants from three to eighteen months of age with moderate to severe non-synostotic positional plagiocephaly, including plagiocephalic-, brachycephalic-, scaphocephalic-shaped heads. Contraindications for use: Infants with synostosis or hydrocephalus.	Intended for medical purposes to apply static or gentle pressure to prominent regions of an infant's cranium to improve cranial symmetry or shape. To treat infants from three to eighteen months of age with moderate to severe non-synostotic positional plagiocephaly, including plagiocephalic-, brachycephalic-, scaphocephalic-shaped heads. Contraindications for use: Infants with synostosis or hydrocephalus.
OTC and/or Rx	Rx	Rx
Clinical Population	Infants age 3-18 months	Infants age 3-18 months
Daily Wear Time	Up to 23 hrs/day	Up to 23 hrs/day
Materials	• Outer shell of 5/32" copolymer plastic • Inner liner of 1/2" polyethylene foam	• Outer shell of 2mm thermoplastic resin, nylon polyamide • Inner liner of 1/2" polyethylene foam

	• Velcro strap, 1 ½" • Chafe and loop, 1 ½” • Speedy rivet, 91X	• Velcro strap, 1 ½" • Chafe and loop, 1 ½” • Speedy rivet, 91X
Production	• Measurement of infant’s head taken by a 3D scanner from which a 3D image is made. • The 3D image is used to produce a positive mold using a routing machine. • Form orthosis from the positive mold of infant’s head.	• Measurement of infant’s head taken by a 3D scanner from which a 3D image is made. • The 3D image is used to produce a positive mold using a routing machine. • Form orthosis from the positive mold of infant’s head.

VI. Technological Characteristics

The polyethylene foam liner used in both proposed and predicate devices remains identical-- this is the device component that maintains skin contact during treatment.

Hanger Cranial Band 3D differs from the predicate device through the material used for the outer shell. The material used comprises of a thermoplastic resin, nylon polyamide, with fusing and detailing agents, and has passed biocompatibility and non-clinical bench tests. Further discussion of the material can be found in Section 12 (Substantial Equivalence Discussion).

VII. Non-Clinical Performance Data

There are no performance standards applicable to the subject device as established by FDA under section 514. Non-clinical test were performed based on typical handling of cranial orthoses.

- Both outer shell and inner foam lining were tested and found to be biocompatible (reference Section 15).
- Tensile stress testing was conducted on the outer shell material of the subject device, in comparison to typical tensile strength values of the predicate device’s outer shell. Average tensile strength value of the Hanger Cranial Band 3D was found to be higher than the copoly plastic values.
- Drop and chemical tests were performed on the outer shell and had passed the attribute acceptance criteria.
- Validation activities were performed and demonstrated that the device can be reliably manufactured with the intended geometry and dimensional tolerances based upon patient-specific scan information.

VIII. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. The predicate device has been on the market for years with a proven safety and efficacy for the use of the device.

IX. Conclusion/Statement of Substantial Equivalence

Hanger Cranial Band 3D has the same intended use as the predicate device, Hanger Cranial Band (K072566). The technological difference do not raise any questions regarding Hanger Cranial Band 3D's safety and effectiveness.

The information provided in this submission supports the substantial equivalence to the predicate device.