March 17, 2025

Cranial Technologies, Inc.
Jeff Riggs
Quality Manager
1405 W Auto Dr, Floor 2
Tempe, Arizona 85284

Re: K244056
Trade/Device Name: DOC Band 3D
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: OAN
Dated: December 31, 2024
Received: December 31, 2024

Dear Jeff Riggs:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2025.03.17 15:50:01 -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

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)*
K244056

Device Name
DOC Band 3D

Indications for Use *(Describe)*
The DOC Band is indicated for use on infants from three to eighteen months of age with moderate to severe non-synostotic cranial deformation, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads, or a combination thereof.

The DOC Band 3D is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic/dolicocephalic- shaped heads, or a combination thereof.

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

Date: 03/17/2025

Applicant: Cranial Technologies, Inc.

Contact Person: Jeff Riggs

Phone: 480-403-6350

Address: 6511 W Frye Rd, Suite 3

Chandler, AZ 85226

Trade Name: DOC Band 3D

Common Name: Cranial Orthosis

Device Classification: Class II

Product Code: OAN

Regulation Number: 21 CFR 882.5970

Device Description: The DOC Band 3D is a cranial orthosis intended to treat positional plagiocephaly in infants from 3 to 18 months of age. The band is intended to apply a mild pressure to the prominent regions of an infant's cranium and to improve cranial symmetry, proportion, and/or shape.

Theory of Operation: The DOC Band 3D works by applying a mild holding pressure in regions where the head is already too prominent, while encouraging growth in the adjacent flattened regions. In this manner, the band is used to treat not only craniofacial asymmetry, but also proportionality (length to width ratio) of the head. The band is used from three to eighteen months of age because this is the period of rapid brain growth. After two years of age, skull growth stops, and any remaining growth of the cranium is primarily from thickening and hardening of the cranial bones.

Predicate Device(s):

- DOC Band® (K964992)
- DOC Band (K141012)
- DOC Band PostOp™ (K042385)

Substantial Equivalence: The DOC Band 3D is substantially equivalent to the predicate devices. The primary difference is the manufacturing process: the DOC Band 3D utilizes 3D printing technology to fabricate the outer shell, while the predicate devices used vacuum forming. This change allows for greater precision and customization without affecting the device's intended use, safety, or effectiveness.

Intended Use: The DOC Band 3D (band) is a medical device known generically as a cranial orthosis. A cranial orthosis is used to treat a medical condition known as deformational plagiocephaly brachycephaly (DPB).

Indications for Use: The DOC Band is indicated for use on infants from three to eighteen months of age with moderate to severe non-synostotic cranial deformation, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads, or a combination thereof.

The DOC Band 3D is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic/dolicocephalic- shaped heads, or a combination thereof.

Contraindications for Use: The DOC Band 3D is contraindicated for use on infants with craniosynostosis or hydrocephalus.

Summary of Safety and Effectiveness: The DOC Band 3D is made from biocompatible materials that have undergone ISO 10993 testing to ensure safety. Bench testing has demonstrated that the device's mechanical properties meet or exceed those of the predicate devices. The clinical performance of the DOC Band 3D is expected to be comparable to the predicate devices in the treatment of deformational plagiocephaly.

Comparison of DOC Band 3D to Predicate Devices

Feature/Parameter	Predicate Device (DOC Band - K964992, K141012, K042385)	3D Printed Cranial Remodeling Orthosis (DOC Band 3D)
Intended Use	The DOC Band (band) is a medical device known generically as a cranial orthosis. A cranial orthosis is used to treat a medical condition known as deformational plagiocephaly brachycephaly (DPB).	The DOC Band 3D (band) is a medical device known generically as a cranial orthosis. A cranial orthosis is used to treat a medical condition known as deformational plagiocephaly brachycephaly (DPB).
Indications for Use	The DOC Band is indicated for use on infants from three to eighteen months of age with moderate to severe non-synostotic cranial deformation, including infants with plagiocephalic-, brachycephalic-, and	The DOC Band 3D is indicated for use on infants from three to eighteen months of age with moderate to severe non-synostotic cranial deformation, including infants with plagiocephalic-, brachycephalic-, and

Feature/Parameter	Predicate Device (DOC Band - K964992, K141012, K042385)	3D Printed Cranial Remodeling Orthosis (DOC Band 3D)
	scaphocephalic-shaped heads, or a combination thereof. The DOC Band PostOp is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic/dolicocephalic-shaped heads.	scaphocephalic-shaped heads, or a combination thereof. The DOC Band 3D is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic/dolicocephalic-shaped heads.
Materials: Outer Shell	Semi-rigid copolymer (polypropylene-ethylene)	Semi-rigid polyamide (3D printed)
Materials: Inner Layer	Lightweight polyethylene foam	Lightweight polyethylene foam
Manufacturing Process	Vacuum forming over a milled plaster model	3D printing
Biocompatibility	Biocompatible materials tested	Biocompatible materials tested
Bench Testing	Mechanical properties tested	Mechanical properties tested; meets or exceeds predicate performance
Sizing	Customized for each patient	Customized for each patient
Fitting and Adjustment	Custom-fit by clinician, adjustments as needed	Custom-fit by clinician, adjustments as needed

Test Summary of Non-Clinical Data

To ensure substantial equivalence of their mechanical forces, the predicate DOC Band and proposed DOC Band 3D both underwent mechanical testing of their shear, flexural, stiffness, fatigue and bond strength. Senior clinicians evaluated the proposed device against the predicate device to confirm equivalent donning and doffing procedures, trims and adjustment procedures, demonstrating substantial equivalence in the fit and treatment protocols. The new material in the proposed device (as compared to the predicate) is the outer shell. It is a polyamide 12 resin, which was tested per ISO 10993 for cytotoxicity, irritation and sensitization, passing all tests per standards.

Conclusion: The DOC Band 3D is substantially equivalent to the predicate device.