August 30, 2024

Invent Medical USA, LLC
Jiri Rosicky
CEO
1800 Mearns Road, Suite Y
Warminster, Pennsylvania 18974

Re: K241957
Trade/Device Name: Talee, Talee PostOp
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: MVA, OAN
Dated: July 1, 2024
Received: July 3, 2024

Dear Jiri Rosicky:

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: 2024.08.30 13:48:40 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
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Office of Product Evaluation and Quality
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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)*

K241957

Device Name

Talee, Talee PostOp

Indications for Use *(Describe)*

The Talee and the Talee PostOp are the Cranial Remolding Orthoses intended for medical purposes for infants from 3 to 18 months of age with moderate-to-severe cranial deformities.
The Talee is used for infants from 3 to 18 months with moderate-to-severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic- shaped heads and combination of these defects.
The Talee PostOp is used for infants from 3 to 18 months of age whose synostosis has been surgically corrected, but who still have 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.

510(k) Summary

Submitter: Invent Medical USA, LLC
Address: 1800 Mearns Rd, Suite Y, Warminster, PA 18974, USA
Phone number: 1 (267) 368-8165
Contact person: Jiri Rosicky
Phone number: 1 (267) 368-8165

Date: August 30, 2024

Submission Type: Traditional 510(k)
Trade name: Talee, Talee PostOp
Common name: Cranial Orthosis
Product Code: MVA, OAN Cranial Orthosis
Regulation: 21 CFR 882.5970, Cranial Orthosis, Class II

Substantial equivalence claimed to predicate device: Talee, Talee PostOp (K230444)

Reference device: Talee, Talee PostOp (K220681)

Device Description:

The Talee and the Talee PostOp are **Cranial Remolding Orthoses** which are individually designed and manufactured **medical devices class II**.

The Cranial Remolding Orthosis (Talee/Talee PostOp) has contact with the head in the prominent regions, an a precisely pre-defined internal space in the areas where flattening occurs. The skull only has the possibility to grow into that pre-defined space, which as a result improves the cranial symmetry and/or physiological shape. The same cranial remolding principle is applied to patients with positional plagiocephaly and to post-operative patients.

The Cranial Remolding Orthosis is made individually as a patient-specific device according to the type of deformity and disposition of the patient. The adjustments are made to the device as needed to accommodate growth and/or optimize the function of the Cranial Orthosis.

The Cranial Remolding Orthosis is made by 3D printing from thermoplastic material with inner soft foam layer.

Indications for Use:

The **Talee** and the **Talee PostOp** are Cranial Remolding Orthoses, intended for medical purposes, for infants from 3 to 18 months of age with moderate-to-severe cranial deformities.

The **Talee** is used for infants from 3 to 18 months with moderate-to-severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads and a combination of these defects.

The **Talee PostOp** is used for infants from 3 to 18 months of age whose synostosis has been surgically corrected, but who still have cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

Technological Characteristics – Basis for Substantial Equivalence

The Cranial Remolding Orthoses Talee and Talee PostOp are substantially equivalent to the predicate medical devices based on the technological characteristics including:

- Indication for use
- Intended use
- Basic remolding principles
- Basic device design

The table below show the comparison between the Cranial Remolding Orthosis Talee/Talee PostOp and the predicate medical device features and approved 3D scanners (Table 1).

Table 1 - Comparison of Predicate Device including Approved Scanners cleared in K230444 to Proposed Device

Feature	Proposed Device	Predicate Device	Evaluation of difference
Trade Name **Common Name**	Talee, Talee PostOp Cranial Orthosis	Talee, Talee PostOp Cranial Orthosis	**IDENTICAL**
Product Code	MVA, OAN	MVA, OAN	**IDENTICAL**
510(k)	K241957	K230444	
Manufacturer	Invent Medical USA, LLC	Invent Medical USA, LLC	**IDENTICAL**
Intended Use	The Cranial Remolding Orthosis has contact with the head in prominent regions where there is contact pressure, while leaving precise, pre-defined internal spaces in areas where there is flattening. To improve cranial symmetry and/or physiological shape, the skull only has the possibility for growth in that pre-defined space.		**IDENTICAL**
Contraindications Talee	Not for use on infants with craniosynostosis, hydrocephalus, microcephaly, younger than 3 months, Older than 18 months		**IDENTICAL**
Prescription	Prescription Use Only		**IDENTICAL**
Sizes	The Cranial Remolding Orthosis has a patient-specific device size/shape based on 3D scan of patient's head		**IDENTICAL**
Software Used for Shape Modification	The modified shape of the infant's symmetrical head shape is created in CAD software from the 3D scan to improve its symmetry and shape. CAD model of the the Orthosis is used for manufacturing by 3D printing.		**IDENTICAL**
Product Design	The Cranial Orthosis is assembled from two-part outer 3D printed shells and the inner soft foam layer. Inner soft foam layer is made from polyethylene foam, which ensures soft contact with the skin of the child's head. On the left/right side of the orthosis there is a fastening mechanism, which is used for easy donning/doffing of the Cranial Orthosis. A set of replaceable contoured shell layers is added to outer shell structure.	The Cranial Orthosis is assembled from two-part outer 3D printed shells and the inner soft foam layer. Inner soft foam layer is made from polyethylene foam, which ensures soft contact with the skin of the child's head. On the left/right side of the orthosis there is a fastening mechanism, which is used for easy donning/doffing of the Cranial Orthosis.	The design changes of Talee, Talee PostOp proposed device **do not affect the intended use, the safety of the medical device or the effectiveness of treatment** of the predicate Talee, Talee PostOp cleared in K230444.
Product Weight	The weight of a Talee orthosis varies from approx. 155 to 250g (5 to 8 oz) Talee PostOp orthosis weight varies from approx. 215 to 370g (7 to 12 oz)		**IDENTICAL**

Material – Inner Layer	• Polyethylene foam	• Polyethylene foam	**IDENTICAL**
Material – 3D Printed Parts	• Thermoplastic materials (the same as in K230444) • New PA material	• Thermoplastic materials	**No risk for change.** Differences in 3D printed parts materials **do not affect intended use, safety of medical device or effectiveness of treatment.** Toxicological Risk and Assessment was performed with new PA material.
Production	• The Orthosis is assembled from outer shell and inner soft foam parts. • The outer shell of the Orthosis is produced by 3D printing, based on CAD model. • CAD model is based on modified shape of infant's head. • Modified shape of infant's head in CAD software is created from the data from 3D scanners		**IDENTICAL**
Approved 3-Dimensional Imaging Devices	• Omega Scanner • 3dMDhead System • 3dMDflex System • M4DScan/BodyScan System • Spectra 3D Scanner • Creaform HCP • Creaform Peel 1 • Creaform Peel 2 (=Peel 3D) • Artec Eva • Artec Eva Lite • EinScan H • EinScan H2	• Omega Scanner • 3dMDhead System • 3dMDflex System • M4DScan/BodyScan System • Spectra 3D Scanner • Creaform HCP • Creaform Peel 1 • Creaform Peel 2 (=Peel 3D) • Artec Eva • Artec Eva Lite • Einscan H	**No risk for change.** Scanner used with proposed device was found compatible with predicate device K230444
Testing	Non – clinical performance testing: • Impact Strength mechanical test • Structural Stiffness mechanical • Biocompatibility evaluation – Plastazote, new PA material • Accuracy Test – Manufacturing of Cranial Remolding Orthosis • Manufacturing Test – Accuracy of Laser Plotter • Toxicological tests	Non – clinical performance testing: • Impact Strength mechanical test • Structural Stiffness mechanical • Biocompatibility evaluation – Plastazote • Accuracy Test – Manufacturing of Cranial Remolding Orthosis • Manufacturing Test – Accuracy of Laser Plotter	**No risk of change** Identical methodology for performance testing showing similar results. New toxicological test and risk assessment.
Biocompatibility	Biocompatibility Testing • Cytotoxicity • Sensitization • Irritation • Leachable substances	Biocompatibility Testing • Cytotoxicity • Sensitization • Irritation	**No risk of change** Risk assessment of leachable substances

Test Summary

The following non-clinical tests were conducted for Talee and Talee PostOp and are valid for both proposed and predicate devices. The predetermined acceptance criteria were met:

- Sensitization testing per ISO 10993-10:2010 (Recognition Number: 2-174)
- Cytotoxicity testing per ISO 10993-5:2009 (Recognition Number: 2-245)
- Irritation testing per ISO 10993-10:2010 (Recognition Number: 2-174)
- Accuracy and Capabilities Study
- Impact strength mechanical test
- Structural stiffness mechanical test
- Manufacturing Test – Dimensional Accuracy of Laser Plotter
- Accuracy Test – Manufacturing of Cranial Remolding Orthosis
- New material PA (polyamide) inhalation and dermal exposure (off-gassing and wipe tests)
- Biological evaluation of medical devices ISO 10993-1: Fifth edition 2018-08 - Part 1: Evaluation and testing within a risk management process (Recognition Number: 2-258)
- Biological evaluation of medical devices ISO 10993-17 First edition 2002-12-01 and ISO 10993-17 Second edition 2023-09 - Part 17: Establishment of allowable limits for leachable substances (Recognition Number: 2-237 and 2-303)

Conclusion

The Talee, Talee PostOp has identical indications for use as the predicate device in K230444. The fundamental technological characteristics of the Talee, Talee PostOp 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 upon the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the subject device Talee/Talee PostOp is substantially equivalent to the predicate device under the Federal Food, Drug and Cosmetic Act.