September 22, 2022

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

Re: K220681
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: August 22, 2022
Received: August 23, 2022

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 (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)*

K220681

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.

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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 prepared: September 22, 2022

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: STARband, STARlight (K151979)

Reference devices: STARband, STARlight (K142141)
Boston Band (K111609)

Description:

Product classification and indication for use

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

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 ages 3 to 18 months with moderate-to-severe, non-synostotic, positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic- shaped heads or a combination of these defects.

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

Remolding principle

The Cranial Remolding Orthosis (Talee/Talee PostOp) has contact with the head in the prominent regions, and 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.

During treatment, the Cranial Orthosis is checked regularly by a physician/clinician to ensure proper treatment at all times. The infant is evaluated monthly by the clinician to monitor growth and ensure that a

precise fit is maintained. Adjustments are made to the device as needed to accommodate growth and/or optimize the function of the Cranial Orthosis.

Manufacturing process

The Cranial Remolding Orthosis is made individually as a patient-specific device according to the type of deformity and disposition of the patient.

The Cranial Orthosis is made according to the 3D scan of the infant´s head. The shape of the baby's head is scanned by a non-contact optical light 3D scanner that does not have any side effects on the child's health (see the list of approved scanners in Table 4).

The modified shape of the infant's symmetrical head shape is created in CAD software (R4D CADCAM software, Rodin4D, http://rodin4d.com/en/Products/rectification) from the 3D scan.

CAD model of the outer shell of the Orthosis is based on modified shape of infant's head. The outer shell of the Orthosis is produced by 3D printing (industrial HP MJF 3D printers). 3D printed shell provides stiffness of the Orthosis and the control of the desired head shape.

The Cranial Orthosis is assembled from two-part outer 3D printed shell and the inner soft foam layer. Inner soft foam layer is made from polyethylene foam (Plastazote), which ensures soft contact with the skin of the child's head. The Plastazote is held in place by double sided tape. On the left/right side of the orthosis there is a fastening mechanism, which is used for easy donning/doffing of the Cranial Orthosis.

Specification of Materials

Talee - Outer shell:
3D printed perforated and contoured multi-layer shell structure from nylon (PA11, PA12 or CB PA12), thickness varies from 0.8mm (1/32") to 4mm (5/32")
Talee - Inner material:
Polyethylene foam (Plastazote), thickness varies from 3mm (1/8") to 12mm (1/2")
Talee - Adjustment pads material (optional):
Oval pads – Polyethylene foam (Plastazote) thickness varies from 2mm (1/12") to 4mm (1/6")
Foam pad - Polyethylene foam (Plastazote) & Polyurethane elastic foam/ Thermoplastic polyurethane, thickness varies from 3mm (1/8") to 19mm (3/4"). Plastazote material at skin contacting side.

Talee PostOp - Outer shell:
3D printed perforated and contoured multi-layer shell structure from nylon (PA11, PA12 or CB PA12), thickness varies from 0.8mm (1/32") to 6mm (1/4")
Talee PostOp - Inner material:
Polyethylene foam (Plastazote), thickness varies from 3mm (1/8") to 12mm (1/2")
Talee PostOp - Adjustment pads material (optional):
Oval pads – Polyethylene foam (Plastazote) thickness varies from 2mm (1/12") to 4mm (1/6")
Foam pad - Polyethylene foam (Plastazote) & Polyurethane elastic foam/ Thermoplastic polyurethane, thickness varies from 3mm (1/8") to 19mm (3/4"). Plastazote material at skin contacting side.

Talee and Talee PostOp - Fastening mechanism:
Self-locking clip mechanism on left/right sides, 3D printed clip combined with BOA lanyard or Rubber band.

Product fitting, adjustments and reporting software

The Cranial Remolding Orthosis is provided by a Certified Orthotist (CO) solely on the order (prescription) of a licensed physician. During treatment, the Cranial Orthosis Talee and Talee PostOp is regularly checked by

a physician/clinician to ensure proper treatment at all times. During an initial fitting and also at every follow up, the clinician will assess the need for further adjustments made by adding stabilization pads or removing them. All components are assembled into the final finished product manually. Any assembly or adjustments are always done by a specifically trained professional.
The infant is evaluated monthly by the clinician to monitor growth and ensure that a precise fit is maintained. Adjustments are made to the device as needed to accommodate growth and/or optimize the function of the Cranial Orthosis. Cranial Comparison App (CCA) is a separate reporting software program designed to present specific measurements derived from a 3D digital model of the patient's cranium. The CCA does not affect the operation of the approved scanners (see the list of approved scanners). The CCA is not used for manufacturing of the Talee or Talee PostOp.

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:

The Cranial Remolding Orthoses Talee and Talee PostOp are substantially equivalent to the predicate medical devices. It is a Cranial Orthosis designed individually for each patient based on a 3D scan of the baby's head. The intended use is the same - the treatment of head shape deformities at a crucial growing period of an infant's life. The remolding principle of the Cranial Orthosis is the same.

The tables below show the comparison between Cranial Remolding Orthosis Talee/Talee PostOp and predicate Medical device features and Approved 3D scanners (Table 1). Other tables below show the comparison between Cranial Remolding Orthosis Talee/Talee PostOp and reference Medical devices, including Reporting Software (Table 2), other Approved 3D scanners and CAD design software (Table 3).

Table 1 - Comparison of Predicate Device including Approved Scanners cleared in K151979 to proposed device

Feature	**K151979 STARband, STARlight**	**Proposed Device**	**Evaluation of difference**
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.	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.	**SAME**

Materials	Material for STARband Side Opening design and STARband Bi-Valve design • Outer shell of 5/32” copolymer plastic • An inner liner of 1/2” Pelite polyethylene foam or 1/2" Aliplast foam Material for STARlight Side Opening design and STARlight Bi-Valve design • 5/32” - 1/4” clear Surlyn or 1/8” – 7/32” Clear Co-Polyester plastic shell Material for STARlight PRO design • 1/4” – 3/8” clear Surlyn Closure for Bivalve design • Sliding/Overlap closure system • Chicago screw (or similar) for top sliding mechanism • 1” Velcro strap • 1” chafe buckle • Speedy rivets Closure for STARband Side Opening design • 1 ½” Velcro Strap • 1 ½” chafe buckle • A Gap Block made from ½” firm Pelite polyethylene foam • Large Flange, Blind Rivet Closure for STARlight Side Opening design and the STARlight PRO design: • 1” Velcro Strap • 1” chafe buckle • Optional tamper resistant strap (qty 2 for the STARlight PRO design)	**Talee Outer Shell:** 3D printed perforated and contoured multi-layer shell structure from Polyamide/Nylon (PA11, PA12 or CB PA12), thickness varies from 0.8 mm (1/32") to 4 mm (5/32") with optional water-based color coating. **Talee Inner Material:** Polyethylene foam (Plastazote) Polyethylene foam, thickness varies from 3 mm (1/8") to 12 mm (1/2") **Adjustment pad material (optional):** Polyethylene foam (Plastazote) & Polyurethane elastic foam/ TPU, thickness varies from 3mm (1/8") to 19mm (3/4") **Talee PostOp Outer Shell:** 3D printed perforated and contoured multi-layer shell structure from Polyamide/Nylon (PA11, PA12 or CB PA12), thickness varies from 0.8 mm (1/32") to 6 mm (1/4") with optional water-based color coating. **Talee PostOp Inner Material:** Polyethylene foam (Plastazote) Polyethylene foam, thickness varies from 3 mm (1/8") to 12 mm (1/2") **Adjustment pad material (optional):** Polyethylene foam (Plastazote) & Polyurethan elastic foam/TPU, thickness varies from 3mm (1/8") to 19mm (3/4") **Closure Mechanism (Talee, Talee PostOp):** Self-locking clip mechanism on left/right sides, 3D printed clip combined with BOA lanyard or Rubber Band	**No risk for change.** Inner liner material (contact with intact skin): **Similar** All devices’ inner liners are manufactured from a variety of polyethylene foams. Outer shell and Interlayer materials: Differences in materials used for Cranial Orthosis **do not affect intended use, safety of medical device or effectiveness of treatment.** All materials have been previously used for medical applications and are not expected to cause any adverse events when in contact with skin or hair.

Product design	Custom made Cranial Orthosis, approximately 6 to 10oz in weight. STARlight PRO weighs 12.5 to 18.5 oz.	The Cranial Remolding Orthoses, Talee and Talee PostOp, are made individually as a patient-specific device. 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).	**No risk for change.** Differences in product design of Cranial Orthosis **do not affect intended use, safety of medical device or effectiveness of treatment.** Talee/Talee PostOp orthoses are lighter than predicated devices.
Production	• 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	• 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 (see the list of approved scanners – Table 4).	**No risk for change.** Differences in production of Cranial Orthosis **do not affect intended use, safety of medical device or effectiveness of treatment.**
Approved 3-Dimensional Imaging Devices	• STARscanner I • STARscanner II • Omega Scanner • scanGogh-II • 3dMDhead System • 3dMDcranial System • 3dMDflex System • SmartSoc System • M4DScan/BodyScan System • Spectra 3D Scanner	**FDA 510k cleared devices:** • Omega Scanner (K151979, K111609) • 3dMDhead System (K151979) • 3dMDflex System (K151979) • M4DScan/BodyScan System (K151979) • Spectra 3D Scanner (K151979)	**SAME** We only use scanners cleared by predicate: K151979 or reference: K111609
Testing		Non – clinical performance testing: • Impact Strength mechanical test • Structural Stiffness mechanical test • Biocompatibility evaluation – Plastazote • Accuracy Test – Manufacturing of Cranial Remolding Orthosis • Manufacturing Test – Accuracy of Laser Plotter	

Table 2 - Comparison of Reference Device including Reporting Software cleared in K142141 to proposed device

Feature	K142141 STARband, STARlight	Proposed Device	Evaluation of difference

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.	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. The same Cranial Remolding principle is applied to patients with positional plagiocephaly and to post-operative patients.	**SAME**
Materials	Material for STARband Side Opening design and STARband Bi-Valve design • Outer shell of 5/32" copolymer plastic • An inner liner of 1/2" Pelite polyethylene foam or 1/2" Aliplast foam Material for STARlight Side Opening design and STARlight Bi-Valve design • 5/32" - 1/4" clear Surlyn or 1/8" – 7/32" Clear Co-Polyester plastic shell Material for STARlight PRO design • 1/4" – 3/8" clear Surlyn Closure for Bivalve design • Sliding/Overlap closure system • Chicago screw (or similar) for top sliding mechanism • 1" Velcro strap • 1" chafe buckle • Speedy rivets Closure for STARband Side Opening design • 1 ½" Velcro Strap • 1 ½" chafe buckle • A Gap Block made from ½" firm Pelite polyethylene foam • Large Flange, Blind Rivet Closure for STARlight Side Opening design and the STARlight PRO design: • 1" Velcro Strap • 1" chafe buckle • Optional tamper resistant strap (qty 2 for the STARlight PRO design)	**Talee Outer Shell:** 3D printed perforated and contoured multi-layer shell structure from Polyamide/Nylon (PA11, PA12 or CB PA12), thickness varies from 0.8 mm (1/32") to 4 mm (5/32") with optional water-based color coating. **Talee Inner Material:** Polyethylene foam (Plastazote) Polyethylene foam, thickness varies from 3 mm (1/8") to 12 mm (1/2") **Adjustment pad material (optional):** Polyethylene foam (Plastazote) & Polyurethane elastic foam/TPU, thickness varies from 3mm (1/8") to 19mm (3/4") **Talee PostOp Outer Shell:** 3D printed perforated and contoured multi-layer shell structure from Polyamide/Nylon (PA11, PA12 or CB PA12), thickness varies from 0.8 mm (1/32") to 6 mm (1/4") with optional water-based color coating. **Talee PostOp Inner Material:** Polyethylene foam (Plastazote) Polyethylene foam, thickness varies from 3 mm (1/8") to 12 mm (1/2") **Adjustment pad material (optional):** Polyethylene foam (Plastazote) & Polyurethane elastic foam/TPU, thickness varies from 3mm (1/8") to 19mm (3/4") **Closure Mechanism (Talee/Talee PostOp):** Self-locking clip mechanism on left/right sides, 3D printed clip combined with BOA lanyard or Rubber Band	**No risk for change.** Inner liner material (contact with intact skin): **Similar** All devices' inner liners are manufactured from a variety of polyethylene foams. Outer shell and Interlayer materials: Differences in materials used for Cranial Orthosis **do not affect intended use, safety of medical device or effectiveness of treatment.** All materials have been previously used for medical applications and are not expected to cause any adverse events when in contact with skin or hair.

Product design	Custom made Cranial Orthosis, approximately 6 to 10oz in weight. STARlight PRO weighs 12.5 to 18.5 oz.	The Cranial Remolding Orthoses, Talee and Talee PostOp, are made individually as a patient-specific device. 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).	**No risk for change.** Differences in product design of a Cranial Orthosis **do not affect intended use, safety of medical device or effectiveness of treatment.** Talee/Talee PostOp orthoses are lighter than reference devices.
Production	• 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	• 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 (see the list of approved scanners – Table 4).	**No risk for change.** Differences in production of Cranial Orthosis **do not affect intended use, safety of medical device or effectiveness of treatment.**
Approved 3-Dimensional Imaging Devices	• STARscanner I • STARscanner II • Omega Scanner • scanGogh-II • 3dMDhead System • 3dMDcranial System • 3dMDflex System	**FDA 510k cleared devices:** • Omega Scanner (K151979, K111609) • 3dMDhead System (K151979) • 3dMDflex System (K151979) • M4DScan/BodyScan System (K151979) • Spectra 3D Scanner (K151979)	**SAME** We only use scanners cleared by predicate: K151979 or reference: K111609
Reporting Software	Cranial Comparison Utility (CCU) The CCU is a separate software program designed to present specific measurements derived from a 3D digital model of the patient's cranium. The CCU does not affect the operation of the STARscanner and is not used for manufacturing of the STARband or STARlight.	Cranial Comparison App (CCA) The CCA is a separate software program designed to present specific measurements derived from a 3D digital model of the patient's cranium. The CCA does not affect the operation of the approved scanners (see the list of approved scanners). The CCA is not used for manufacturing of the Talee or Talee PostOp.	**SAME**

Testing	CCU Accuracy and Capabilities Study - Utilized a representative cranial shape that possesses a predefined shape with known dimensions - Compared CCU to manual measurements and 3D-CAD sw - Accessed accuracy of measurements and capabilities of model alignment, differential maps, calculations and reporting	CCA Accuracy and Capabilities Study - Utilized a representative cranial shape that possesses a predefined shape with known dimensions - Compared CCA to manual measurements and 3D-CAD software - Accessed accuracy of measurements and capabilities of model alignment, differential maps, calculations and reports	**SAME**

Table 3 - Comparison of Reference Device including CAD design cleared in K111609 to proposed device

Feature	**K111609 Boston Band**	**Proposed Device**	**Evaluation of difference**
Intended Use	Intended for medical purposes to passively hold prominent cranial regions of an infant's skull in order to improve cranial proportion and symmetry in infants from three to eighteen months of age, with nonsynostotic positional plagiocephaly, including infants with plagiocephic, brachycephalic and scaphocephalic patterned head shapes. The device 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-shaped heads.	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 ages 3 to 18 months with moderate-to-severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic- shaped heads or a combination of these defects. The Talee PostOp is used for infants ages 3 to 18 months whose synostosis has been surgically corrected, but who still have cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.	**SAME**

Materials	• outer shell of thermoformable plastic (1/4 or 3/16 copolymer plastic) • a single layer of ½ inch or 5-6 layers of 1/8 inch, or a combination of 1 - 2 1/4 inch layers with 1/8 inch layers of pelite hypoallergenic polyethylene foam or Aliplast • Velcro strap (pile) sticky back Velcro hook	**Talee Outer Shell:** 3D printed perforated and contoured multi-layer shell structure from Polyamide/Nylon (PA11, PA12 or CB PA12), thickness varies from 0.8 mm (1/32") to 4 mm (5/32") with optional water-based color coating. **Talee Inner Material:** Polyethylene foam (Plastazote) Polyethylene foam, thickness varies from 3 mm (1/8") to 12 mm (1/2") **Adjustment pad material (optional):** Polyethylene foam (Plastazote) & Polyurethane elastic foam/TPU, thickness varies from 3mm (1/8") to 19mm (3/4") **Talee PostOp Outer Shell:** 3D printed perforated and contoured multi-layer shell structure from Polyamide/Nylon (PA11, PA12 or CB PA12), thickness varies from 0.8 mm (1/32") to 6 mm (1/4") with optional water-based color coating. **Talee PostOp Inner Material:** Polyethylene foam (Plastazote) Polyethylene foam, thickness varies from 3 mm (1/8") to 12 mm (1/2") **Adjustment pad material (optional):** Polyethylene foam (Plastazote) & Polyurethane elastic foam/TPU, thickness varies from 3mm (1/8") to 19mm (3/4") **Closure Mechanism (Talee/ Talee PostOp):** Self-locking clip mechanism on left/right sides, 3D printed clip combined with BOA lanyard or Rubber Band	**No risk for change.** Inner liner material (contact with intact skin): **Similar** All devices' inner liners are manufactured from a variety of polyethylene foams. Outer shell and Interlayer materials: Differences in materials used for Cranial Orthosis **do not affect intended use, safety of medical device or effectiveness of treatment.** All materials have been previously used for medical applications and are not expected to cause any adverse events when in contact with skin or hair.
Product design	Cranial Orthosis - made to individual's specifications	The Cranial Remolding Orthosis is made individually as a patient-specific device.	**SAME**

Production	• Model of the infants head from a negative impression (cast) of the infants head • Scan of the infants head from a Fastscan hands free class II laser scanner • Scan of the infants head using a Fastscan handheld class I laser scanner • Scan of the infants head using the Creaform class I laser scanner sold as Ohio Willow Wood Omega / handycam • Foam model of the infants head carved using an industry standard 5 axis scanner	• 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 (see the list of approved scanners – Table 4).	**No risk for change.** Differences in production of Cranial Orthosis **do not affect intended use, safety of medical device or effectiveness of treatment.**
	The same CAD-CAM software, Rodin 4D, is used for 3D rectification. More information in "Summary and Conclusion of Non-Clinical Performance Data" (K111609).		
Approved 3-Dimensional Imaging Devices	• Fastscan (class II laser) • Fastscan II (class I laser) • Omega Scanner	**FDA 510k cleared devices:** • Omega Scanner (K151979, K111609) • 3dMDhead System (K151979) • 3dMDflex System (K151979) • M4DScan/BodyScan System (K151979) • Spectra 3D Scanner (K151979)	**SAME** We only use scanners cleared by predicate: K151979 or reference: K111609

Table 4 – Comparison of technical parameters of Approved Scanners

3D scanner	Manufacturer	Website	Type	Accuracy (mm)	Resolution (mm)	FDA 510k
OMEGA	Ohio Willow Wood	https://www.willowwoodco.com/	Light scanner	up to 0.50	1.00	K151979
M4D	Rodin4D	http://rodin4d.com/	Light scanner	up to 0.50	1.00	K151979
BodyScan	Techmed3D	https://techmed3d.com	Light scanner	up to 0.50	1.00	K151979
Spectra	VORUM	https://vorum.com/	Light scanner	0.10	N/A	K151979
3dMDhead System	3DMD	http://www.3dmd.com/	Light scanner	0.20	N/A	K151979
3dMDflex System	3DMD	http://www.3dmd.com/	Light scanner	0.20-0.50	N/A	K151979

Non-clinical performance Testing:

The following Non-clinical performance testing (Table 5) was conducted on Talee and Talee PostOp Cranial Orthoses.

Table 5 – Non-clinical performance testing overview

Tested Area	Performance Testing
Software Cranial Comparison App (CCA)	Accuracy and Capabilities Study
Product Talee/Talee PostOp	Impact strength mechanical test
	Structural stiffness mechanical test
Method Manufacturing	Manufacturing Test – Dimensional Accuracy of Laser Plotter
	Accuracy Test – Manufacturing of Cranial Remolding Orthosis

Biocompatibility evaluation

Non-clinical performance testing included biocompatibility evaluation of materials in contact with intact skin. The results of these tests are in Table 6.

Table 6 – Materials in contact with intact skin

Biocompatibility evaluation – PE foam (Plastazote)		
Test	**Results**	**Conclusions**
ISO Cytotoxicity MEM Elution ISO 10993-5	Cell culture treated with test sample exhibited no reactivity (Grade 0)	Non-cytotoxic
ISO Intracutaneous Irritation ISO 10993-10	Rabbits treated with test samples exhibited no irritation (Scores 0)	Non-irritating
ISO Guinea Pig Maximization Sensitization ISO 10993-10	Albino guinea pigs treated with test sample did not elicit a sensitization response (Grade 0)	Non- sensitizer
The material is in contact with the intact skin of the head. It is necessary to clean and disinfect polyethylene foam (Plastazote) material each day by isopropyl alcohol as described in the Instructions for Use.		

The safety of the Cranial Orthosis is established under standard biocompatibility assessments. These assessments reveal that the device and the materials used are not expected to adversely affect the infants under the intended conditions of wear. (Polyethylene foam is commonly used to line orthoses). The materials are not reported to cause skin irritation or any toxic effects. Further, the product is designed to avoid improper migration or harmful levels of pressure. The interior of the device is smooth and poses no significant threat to the child during application within the normal scope of its intended use.

Test summary and discussion:

The following non-clinical tests were conducted for Talee and Talee PostOp. 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

Discussion

- The Biocompatibility assessments included in the non-clinical performance testing revealed that the proposed device and the materials used are not expected to have adverse effects on the patients under the intended conditions of wear.
- Based on the Accuracy and Capabilities study, the CCA software program met all the acceptance criteria and provides comparable accuracy to manual and CAD method. The CCA also has the same (or greater) capabilities as the manual or CAD method.
- According to the mechanical tests performed, the tested devices Talee and Talee PostOp, have equivalent safety and equivalent (or higher) structural strength than the predicate devices.
- The Manufacturing test and the Accuracy test mentioned above showed that all of the acceptance criteria were met, and the manufacturing process of the finished 3D printed cranial remolding orthosis ensures the required dimensional accuracy and that the devices fit accurately.

Conclusions of non-clinical performance data

- Substantial equivalence, safety, and effectiveness are supported by the Non-clinical Performance Testing (Software, Product, Manufacturing method) of Talee and Talee PostOp to primary predicate devices (STARband, STARlight PRO).
- The non-clinical performance testing mentioned above demonstrates that the differences in technological features of the Cranial Orthosis do not affect performance, safety, or effectiveness of Medical Device Talee/Talee PostOp in comparison to Predicate/Reference Device.

General conclusion:

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.