June 22, 2023

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

Re: K230444
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: May 22, 2023
Received: May 23, 2023

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 -S

Digitally signed by Adam D. Pierce -S
Date: 2023.06.22 10:58:23 -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)*

K230444

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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: June 22, 2023

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 (K220681)

Reference device: MyCRO Band (K201426)

Description:

Product Summary

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

The Talee, Talee PostOp proposed device is identical to the existing predicate Talee, Talee PostOp cleared in K220681. There have been made the following modifications:

- New optional Firm pad manufactured from the same material as outer shell (PA11, PA12 or CB PA12) with Plastazote inner layer material as skin contacting material (cleared in K220681).
- Update in approved 3-dimensional imaging devices

***Discussion of Design Changes and* 3-dimensional imaging devices** *(Proposed device vs. Predicate device* K220681*)*

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 existing predicate Talee, Talee PostOp cleared in K220681.

- The basic product design of the Talee, Talee PostOp proposed device is identical to the product design of the existing predicate Talee, Talee PostOp (K220681).
- Manufacturing process of the Talee, Talee PostOp proposed device is identical to the manufacturing process of the existing predicate Talee, Talee PostOp (K220681).
- Skin contacting material of the Talee, Talee PostOp proposed device is identical to the material of the existing predicate Talee, Talee PostOp (K220681).
- The new optional Firm pad represents new choice to existing foam pads. The skin contacting material Plastazote of Firm pad is the same as skin contacting material of Foam pad used in predicate device.

- The new approved 3D scanners work on identical principle to the previously approved devices. This update is a response to a wider device portfolio on the market.

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 3).

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.
Firm pad - Polyamide pad made by 3D printing (PA11, PA12 or CB PA12), thickness varies from 0.8mm (1/32") to 6mm (1/4"). 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.
Firm pad - Polyamide pad made by 3D printing (PA11, PA12 or CB PA12), thickness varies from 0.8mm (1/32") to 6mm (1/4"). 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/reference 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 identical - the treatment of head shape deformities at a crucial growing period of an infant's life. The remolding principle of the Cranial Orthosis is identical.

The tables 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 2 below shows the comparison between the Cranial Remolding Orthosis Talee/Talee PostOp and the reference medical device, including another approved 3D scanners in previously cleared 3D printed cranial orthosis.

Table 1 - Comparison of Predicate Device including Approved Scanners cleared in K220681 to Proposed Device

Feature	**Talee, Talee PostOp** **Proposed Device**	**K220681** **Talee, Talee PostOp** **Predicate Device**	**Evaluation of difference**
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**
Materials			
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.	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.	**IDENTICAL**
Talee Inner Material:	Polyethylene foam (Plastazote) Polyethylene foam, thickness varies from 3 mm (1/8") to 12 mm (1/2")	Polyethylene foam (Plastazote) Polyethylene foam, thickness varies from 3 mm (1/8") to 12 mm (1/2")	**IDENTICAL**
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.	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.	**IDENTICAL**
Talee PostOp Inner Material:	Polyethylene foam (Plastazote) Polyethylene foam, thickness varies from 3 mm (1/8") to 12 mm (1/2")	Polyethylene foam (Plastazote) Polyethylene foam, thickness varies from 3 mm (1/8") to 12 mm (1/2")	**IDENTICAL**
Adjustment pad material (Talee, Talee PostOp) (optional):	Polyethylene foam (Plastazote) & Polyurethan elastic foam/TPU/ PA11, PA12, CB PA12, thickness varies from 0.8mm (1/32") to 19mm (3/4")	Polyethylene foam (Plastazote) & Polyurethan elastic foam/TPU, thickness varies from 3mm (1/8") to 19mm (3/4")	Differences in interlayer 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

Closure Mechanism (Talee, Talee PostOp):	Self-locking clip mechanism on left/right sides, 3D printed clip combined with BOA lanyard or Rubber Band	Self-locking clip mechanism on left/right sides, 3D printed clip combined with BOA lanyard or Rubber Band	**IDENTICAL**
Product design	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).		**IDENTICAL**
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	• Omega Scanner • 3dMDhead System • 3dMDflex System • M4DScan/BodyScan System • Spectra 3D Scanner	Scanners used with proposed device were either found compatible with predicate: K220681 or reference: K201426 and passed V&V processes.
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 Approved scanners cleared in K201426 to Proposed Device

Feature	**Talee, Talee PostOp Proposed Device**	**K201426 MyCRO Band Reference Device**	**Evaluation of difference**
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	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.	**IDENTICAL**

	possibility for growth in that pre-defined space.		
Materials			
Outer Shell:	**Talee, Talee PostOp:** 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.	The orthosis is made of thermoplastic material Polyamide PA12 with a soft, washable padded lining on the interior.	Differences in outer and inner layer 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.
Inner Material:	**Talee, Talee PostOp:** Polyethylene foam (Plastazote) Polyethylene foam, thickness varies from 3 mm (1/8") to 12 mm (1/2")		
Adjustment pad material:	**Talee, Talee PostOp (optional):** Polyethylene foam (Plastazote) & Polyurethan elastic foam/TPU/ PA11, PA12, CB PA12, thickness varies from 0.8mm (1/32") to 19mm (3/4")	N/A	
Closure Mechanism:	**Talee, Talee PostOp:** Self-locking clip mechanism on left/right sides, 3D printed clip combined with BOA lanyard or Rubber Band	One sided 3D printed closure mechanism combined with elastic band	The mechanisms are **similar**. Closure mechanism of proposed device has been previously approved in predicate device K220681.
Product design	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).	Polymer helmet with side opening closure and padded lining 4 – 6.5 oz Patient-matched sizing by scanning an image of patient's head shape	Differences in product design of a Cranial Orthosis **do not affect intended use, safety of medical device or effectiveness of treatment.**
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.	Additively manufacture the orthosis based upon measurements of the infant's head taken by a previously cleared 3-dimensional imaging device	**IDENTICAL**

	• Modified shape of infant's head in CAD software is created from the data from 3D scanners (see the list of approved scanners – Table 3).		
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	• Creaform HCP • Creaform Peel1 • Creaform Peel 3D • Rodin4D M4D Scan • TechMed3D BodyScan • OMEGA Scanner 3D • Artec Eva • Artec Eva Lite	Scanners used with proposed device are either cleared by predicate: K220681 or reference: K201426 and passed V&V processes.

Non-clinical performance Testing:

The following Non-clinical performance testing (Table 4) was conducted on Talee and Talee PostOp Proposed Device.

Table 4 – Non-clinical performance testing overview

Tested Area	**Performance Testing**
Product Talee/Talee PostOp	Impact strength mechanical test
	Structural stiffness mechanical test
Method Manufacturing	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 5.

Table 5 – 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 Talee, Talee PostOp Proposed Device is identical to the K220681 Talee, Talee PostOp Predicate Device.

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

Discussion

Talee, Talee PostOp Proposed device is identical to the K220681 Talee, Talee PostOp Predicate device with updates described above.

Full validation and verification (V&V) testing is not necessary for the proposed design changes. New V&V was performed to evaluate the specific design changes to ensure the changes do not alter the safety and effectiveness of the device. All these updates have passed Invent Medical's V&V processes. Overview of the non-clinical performance tests completed for the updates is in table 4.

Above in the test summary you can find an overview of tests performed for K220681 Talee, Talee PostOp predicate device and valid for Talee, Talee PostOp proposed device.

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 comparable safety and comparable (or higher) structural strength than the predicate/reference 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.

The Biocompatibility assessments included in the non-clinical performance testing of the materials in contact with intact skin revealed that these materials used are not expected to have adverse effects on the patients under the intended conditions of wear.

Conclusions of non-clinical performance data

The non-clinical performance testing mentioned above demonstrates that the differences in production of Cranial Orthosis do not affect performance, safety, or effectiveness of Medical Device Talee/Talee PostOp in comparison to K220681 Talee, Talee PostOp predicate device.

We tested Talee, Talee PostOp proposed device compared to the same tested reference device (STARband, STARlight PRO) that we used for performance testing of K220681 Talee, Talee PostOp predicate device.

All the results of this performance testing demonstrate identical conclusions as results of performance testing of cleared Predicate device Talee, Talee PostOp to the same tested reference device (STARband, STARlight PRO).

Substantial equivalence, safety and effectiveness are supported by Non-clinical Performance Testing (Software, Product, Manufacturing method) of Talee, Talee PostOp to primary predicate device (K220681 Talee, Talee PostOp).

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.