April 27, 2021

Orthomerica Products Inc.
Colton Carter
Regulatory and Compliance Engineer
6333 North Orange Blossom Trail
Orlando, Florida 32810

Re: K203098
Trade/Device Name: STARband, STARlight, St. Louis Band
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: OAN, MVA
Dated: January 27, 2021
Received: January 28, 2021

Dear Colton Carter:

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)*
K203098

Device Name
STARband, STARlight, and St. Louis Band Cranial Orthosis

Indications for Use *(Describe)*
The STARband, STARlight, and St. Louis Band are intended for medical purposes for use on infants from 3 to 18 months of age, with moderate-to-severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and/or shape. These devices are also indicated for adjunctive use for infants from 3 to 18 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.

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
K203098

I. Applicant Information

Name:	Orthomerica Products, Inc.
Address:	6333 North Orange Blossom Trail Orlando, FL 32810
Telephone:	(407) 290-6592
Facsimile:	(407) 290-2419

FDA Establishment Registration Number

1058152

Contact Information

Contact Person:	Colton Carter, Regulatory and Compliance Engineer
Address:	6333 North Orange Blossom Trail Orlando, FL 32810
Telephone:	(407) 290-6592
Facsimile:	(407) 290-2419
Email:	ccarter@orthomerica.com
Date:	April 27th, 2021

II. Submission Information

Type:	Traditional 510(k) Submission
Proprietary Name:	STARband®, STARlight®, and St. Louis Band
Classification:	Class II (special controls); OAN; MVA; 21 CFR 882.5970
Classification Name:	Cranial Orthosis

III. Manufacturer Site

Name:	Orthomerica Products, Inc.
Address:	6333 North Orange Blossom Trail Orlando, FL 32810
Telephone:	(407) 290-6592
Facsimile:	(407) 290-2419

FDA Establishment Registration Number: 1058152

IV. Description of Device/Modification

The STARband® and STARlight® redirects the head growth to improve proportion and symmetry. The practitioner takes a plaster impression or 3-dimensional captured image of the infant's head to acquire the existing shape. The mold is sealed and filled with plaster or the 3-dimensional image is carved from a rigid polyurethane foam blank to create a positive model of the head shape. The positive model is modified to obtain greater symmetry and space in the areas of flattening. The STARband® and STARlight® provide total contact over the prominent or bossed areas of the baby's head to discourage growth there. Over the course of treatment, the inside of the band is further modified by the practitioner to provide space for growth to occur in the flat or depressed areas. The shape of the STARband® and STARlight® directs growth into the areas of least resistance and creates a precise pathway for the head shape to improve in symmetry and proportion.

The STARband® and STARlight® product families as it was last cleared in K180109 are essentially still the same devices. The STARband® Side Opening design and STARband® Bi-Valve design is made with an outer shell of 5/32" polyethylene-polypropylene copolymer plastic with an inner liner made of 1/2" pelite polyethylene foam or 1/2" Aliplast foam (closed cell polyethylene). The STARlight® Side Opening design and the STARlight® Bi-Valve design are made of a plastic shell of 5/32" – 1/4" clear Surlyn or 1/8" - 7/32" Clear Co-Polyester. The STARlight® PRO (Post-operative Remolding Orthosis) design is made of 1/4" to 3/8" clear Surlyn. Optional Aliplast (closed cell polyethylene) padding is available for the clear plastic bands and in addition, optional Reston (polyurethane – 3M Medical Product) foam is available for the STARlight® PRO design.

The STARband® Side Opening design and the STARlight® Side Opening design has a top opening and a side opening. The band is held in place by a Velcro® strap (1½" for STARband® Side Opening and 1" for STARlight® Side Opening) across the side opening. The STARlight® PRO has two side openings, no top opening, and is held in place by a Velcro strap across each side opening. The STARlight® Bi-Valve design and the STARband® Bi-Valve design consist of two plastic shells that overlap with a superior sliding mechanism. The right and left overlap tabs are connected via a Velcro strap with chafe and loop.

The St. Louis Band (formally known as the O&P Bivalve Molding Helmet in K063395) was last cleared in K180109 by Orthomerica Products Inc. The St. Louis Band is a Bi-Valve design made with an outer shell of 1/4" polyethylene-polypropylene copolymer plastic with an inner liner made of 1/4" Aliplast foam (closed cell polyethylene). The Bi-Valve design consists of two plastic shells that overlap and are held together with rivet fasteners. The St. Louis Band utilizes a Velcro® strap with chafe and loop for a secure fit.

The Cranial Comparison Utility (CCU) is a software component for a previously cleared shape capture method, the STARscanner● Data Acquisition System, distributed by Orthomerica Products, Inc. The CCU is a separate software program that is designed to present specific measurements derived from a three-dimensional (3D) digital model and can be used to compare three-dimensional (3D) digital models during the patient treatment period for the purpose of tracking progress. These presented measurements can be incorporated into the patient assessment.

The proposed addition is a new software component for a previously cleared shape capture method, the NetVirta SmartSoc● Data Acquisition System, distributed by Orthomerica Products, Inc. The new software component is the Measurement Comparison Utility (MCU). The MCU is a separate software program, not used in manufacturing, which is designed to present specific measurements derived from a three-dimensional (3D) digital model and can be used to compare three-dimensional (3D) digital models during the patient treatment period for the purpose of tracking progress. These presented measurements can be incorporated into the patient assessment.

V. Indications for Use and Intended Use

Indications for Use:

The STARband®, STARlight®, and St. Louis Band are intended for medical purposes for use on infants from 3 to 18 months of age, with moderate-to-severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and/or shape. These devices are also indicated for adjunctive use for infants from 3 to 18 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.

Intended Use:

The STARband®, STARlight®, and St. Louis Band are designed to treat infants with abnormal head shapes from age 3 to 18 months and is available by prescription only. Since growth is the driving factor in head shape correction, the infants wear the STARband®, STARlight®, or St. Louis Band for approximately 23 hours per day. The most common head deformities are positional plagiocephaly, brachycephaly, and scaphocephaly. The STARband®, STARlight®, and St. Louis Band have also been cleared to treat unresolved head deformities in patients who have undergone surgery to correct craniosynostosis. The same principles of cranial remolding apply to positional deformities and post-operative patients.

VI. Predicate and Reference Devices

Predicate Device:

- STARband● and STARlight● with Cranial Comparison Utility (CCU) - K142141

Reference Devices:

- St. Louis Band Cranial Orthosis – K161138
- STARband● and STARlight● with SmartSoc – K141842

VII. Summary of Technological Characteristics

The MCU proposed in this 510(k) is an added software program for a previously cleared shape capture method, the SmartSoc● Data Acquisition System, that was cleared for use in the fabrication of the STARband●, STARlight●, and St. Louis Band Cranial Orthosis. The technological characteristics and the underlying principles of operation of the STARband●, STARlight●, and St. Louis Band Cranial Orthosis shall remain exactly the same. The inclusion of the MCU is the focus of this submission and the resulting change is indicated in **Table 1** within the feature section Reporting Software. The addition of the accuracy and capabilities study conducted on the MCU is also indicated in the Testing section.

Table 1.a – Comparison of Predicate Device cleared in K142141 to K203098

Feature	K142141	K203098
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.	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.
Indications	The STARband and STARlight are intended for medical purposes for use on infants from 3 to 18 months of age, with moderate-to-severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and/or shape. The devices are also indicated for adjunctive use for infants from 3 to 18 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 STARband and STARlight are intended for medical purposes for use on infants from 3 to 18 months of age, with moderate-to-severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and/or shape. The devices are also indicated for adjunctive use for infants from 3 to 18 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.
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	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

Feature	K142141	K203098
	- 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)	- 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)
Biocompatibility	All materials have been used extensively in Orthotics and Prosthetics	All materials have been used extensively in Orthotics and Prosthetics
Sterility	Not provided Sterile	Not provided Sterile
Product Design	Custom made cranial orthosis, approximately 6 to 10oz in weight. STARlight PRO weighs 12.5 to 18.5 oz.	Custom made cranial orthosis, approximately 6 to 10oz in weight. STARlight PRO weighs 12.5 to 18.5 oz.
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	- 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
Approved 3-Dimensional Imaging Devices	- STARscanner I - STARscanner II - Omega Scanner - scanGogh-II - 3dMDhead System - 3dMDcranial System - 3dMDflex System	- STARscanner I - STARscanner II - Omega Scanner - scanGogh-II - 3dMDhead System - 3dMDcranial System - 3dMDflex System - M4DScan/BodyScan System - Spectra 3D Scanner - SmartSoc System for Android Device - SmartSoc System for iOS Device
Reporting Software	- Cranial Comparison Utility (CCU)	- Cranial Comparison Utility (CCU) - Measurement Comparison Utility (MCU)

Feature	K142141	K203098
Testing	Repeatability and Reproducibility (R&R) Analysis - Utilized uniform shapes with known dimensions that represent various sizes of pediatric patients between ages 3 to 18 months of age - Compared proposed device to cast and predicate device - Associated parameters includes A-P and M-L - Proposed device is substantially equivalent to predicate device Cranial Shape Capture Accuracy Study - Utilized a representative cranial shape that possesses a predefined shape with known dimensions - Compared proposed device to cast and predicate device - Associated Coordinate Planes (A-P; M-L; P-D and various Radius Parameters; Squareness; Flatness) - Proposed device is substantially equivalent to predicate device 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 software - Accessed accuracy of measurements and capabilities of model alignment, differential maps, calculations and reporting Material Biocompatibility Testing - Cytotoxicity –Agar Diffusion - Closed Patch Sensitization - Primary Dermal Irritation	Repeatability and Reproducibility (R&R) Analysis - Utilized uniform shapes with known dimensions that represent various sizes of pediatric patients between ages 3 to 18 months of age - Compared proposed device to cast and predicate device - Associated parameters includes A-P and M-L - Proposed device is substantially equivalent to predicate device Cranial Shape Capture Accuracy Study - Utilized a representative cranial shape that possesses a predefined shape with known dimensions - Compared proposed device to cast and predicate device - Associated Coordinate Planes (A-P; M-L; P-D and various Radius Parameters; Squareness; Flatness) - Proposed device is substantially equivalent to predicate device 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 software - Accessed accuracy of measurements and capabilities of model alignment, differential maps, calculations and reporting MCU Accuracy and Capabilities Study - Utilized representative cranial shapes that reflect symmetrical and asymmetrical cranial shapes - Compared MCU to manual measurements and 3D-CAD software - Accessed accuracy of measurements and capabilities of model alignment,

Feature	K142141	K203098
		differential maps, calculations and reporting

Table 1.b – Comparison of Reference Device cleared in K161138 to K203098

Feature	From K161138	K203098
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.	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.
Indications	The St. Louis Band is intended for medical purposes for use on infants from 3 to 18 months of age, with moderate-to-severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and/or shape. This device is also indicated for adjunctive use for infants from 3 to 18 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 St. Louis Band is intended for medical purposes for use on infants from 3 to 18 months of age, with moderate-to-severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and/or shape. This device is also indicated for adjunctive use for infants from 3 to 18 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.

Materials	St. Louis Band
	- Sliding/Overlap Closure System
	- Outer shell of 1/4" copolymer plastic
	- An inner liner of 1/4" Aliplast foam
	- Bi-Valve Closure
	  - Sliding/Overlap Closure System
	  - 1" Velcro strap
	  - 1" chafe buckle
	  - Speedy rivets
		St. Louis Band
		- Sliding/Overlap Closure System
		- Outer shell of 1/4" copolymer plastic
		- An inner liner of 1/4" Aliplast foam
		- Bi-Valve Closure
		  - Sliding/Overlap Closure System
		  - 1" Velcro strap
		  - 1" chafe buckle
		  - Speedy rivets

Product Design	Custom made cranial orthosis, approximately 7 to 10oz in weight.	Custom made cranial orthosis, approximately 7 to 10oz in weight.
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	- 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

Feature	From K161138	K203098
	- The 3-dimensional image is used to produce a positive mold using a 5-axis routing machine	- The 3-dimensional image is used to produce a positive mold using a 5-axis routing machine
Approved 3-Dimensional Imaging Devices	- STARscanner II - SmartSoc System	- STARscanner II - SmartSoc System
Reporting Software	None	- Measurement Comparison Utility (MCU)
Testing	Repeatability and Reproducibility (R&R) Analysis - Utilized uniform shapes with known dimensions that represent various sizes of pediatric patients between ages 3 to 18 months of age - Compared proposed device to cast and predicate device - Associated parameters includes A-P and M-L - Proposed device is substantially equivalent to predicate device Cranial Shape Capture Accuracy Study - Utilized a representative cranial shape that possesses a predefined shape with known dimensions - Compared proposed device to cast and predicate device - Associated Coordinate Planes (A-P; M-L; P-D and various Radius Parameters; Squareness; Flatness) - Proposed device is substantially equivalent to predicate device Material Biocompatibility Testing - Cytotoxicity –Agar Diffusion - Closed Patch Sensitization - Primary Dermal Irritation	Repeatability and Reproducibility (R&R) Analysis - Utilized uniform shapes with known dimensions that represent various sizes of pediatric patients between ages 3 to 18 months of age - Compared proposed device to cast and predicate device - Associated parameters includes A-P and M-L - Proposed device is substantially equivalent to predicate device Cranial Shape Capture Accuracy Study - Utilized a representative cranial shape that possesses a predefined shape with known dimensions - Compared proposed device to cast and predicate device - Associated Coordinate Planes (A-P; M-L; P-D and various Radius Parameters; Squareness; Flatness) - Proposed device is substantially equivalent to predicate device MCU Accuracy and Capabilities Study - Utilized representative cranial shapes that reflect symmetrical and asymmetrical cranial shapes - Compared MCU to manual measurements and 3D-CAD software - Accessed accuracy of measurements and capabilities of model alignment, differential maps, calculations and reporting

The STARband®, STARlight®, and St. Louis Band Cranial Orthosis have previously received FDA 510(k) clearance with the SmartSoc® Data Acquisition System under K141842 for the STARband® and STARlight® and under K161138 for the St. Louis Band. The MCU does not affect the operation of the SmartSoc® Data Acquisition System and is not used for manufacturing of the STARband®, STARlight®, or St. Louis Band. The MCU is a separate software program designed to capture specific measurements derived from a 3D digital model of the patient's cranium. The STARband®, STARlight®, and St. Louis Band are the same devices as previously cleared with the predicate devices. The SmartSoc® Data Acquisition System shape capture device has the same technological characteristics. Therefore, the STARband®, STARlight®, and St. Louis Band Cranial Orthosis are substantially equivalent to the predicate device.

The STARband®, STARlight®, and St. Louis Band are essentially the same Cranial Orthosis. The main difference between the STARband®, STARlight®, and St. Louis Band are the materials used to produce them. The STARband®, STARlight®, and St. Louis Band materials have been biocompatibility tested in previous submissions. Since the MCU is a separate software program not used in manufacturing, and the STARband®, STARlight®, and St. Louis Band materials are unchanged, the manufacturing processes remain identical and biocompatibility testing for this submission is leveraged from previous submissions.

VIII. Summary and Conclusions of Non-Clinical Performance Data

The MCU software program provides accurate information of 3D digital models from the SmartSoc® Data Acquisition System. The accuracy and reliability of the SmartSoc® Data Acquisition System has already been proven through accuracy analysis, as well as repeatability and reproducibility (R&R) studies. An accuracy and capability study was conducted on the MCU and was determined to be substantially equivalent to the predicate CCU.