DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 20, 2015

BioArchitects USA, LLC
% Mr. Frank Ferguson
CEO
Ferguson Medical International Device Consultants LLC
332 Laskin Road, Suite 437
Virginia Beach, Virginia 23451

Re: K151692
Trade/Device Name: BioArchitects Patient Specific Cranial/Craniofacial Plate
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GXN
Dated: October 19, 2015
Received: October 20, 2015

Dear Mr. Ferguson:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151692

Device Name
BioArchitects Patient Specific Cranial/Craniofacial Plate

Indications for Use *(Describe)*
The BioArchitects Patient Specific Cranial/Craniofacial Plate implant device is intended to replace bony voids in the cranial and/or craniofacial skeleton (e.g., frontal bone, temporal bone, occipital bone, nasal bone, parietal bone, supraorbital process, lacrimal bone, zygomatic bone, sphenoid bone, ethmoid process, vomer). It is a patient specific device.

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21CFR Part 807.92 for the BioArchitects Patient Specific Cranial/Craniofacial Plate implant device.

DATE PREPARED: 19 November 2015

APPLICANTS NAME AND ADDRESS:

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DEVICE NAME:

Common Name of the Device: Cranial or Craniofacial Plate
Trade/Proprietary Name: BioArchitects Patient Specific Cranial/Craniofacial Plate
Classification: 21 CFR 882.5330 Preformed Nonalterable Cranioplasty Plate
Panel: 84
Product Code: GXN

LEGALLY MARKETED DEVICE TO WHICH BIOARCHITECTS IS CLAIMING SUBSTANTIAL EQUIVALENCE:

Primary Predicate Device: Synthes Patient Specific Cranial/Craniofacial Implant (PSCI) (K053199). Reference Predicate Devices: Biomet HTR-PEKK Patient-Matched Implant (K121818) and Medtronic TiMesh Pre-Shaped Cranial Mesh Implants (K974017).

DEVICE DESCRIPTION:
The BioArchitects Patient Specific Cranial/Craniofacial Plate implant device is a single piece device constructed individually for each patient. It is intended to replace bony voids in the cranial and craniofacial skeleton (e.g., frontal bone, temporal bone, occipital bone, nasal bone, parietal bone, supraorbital process, lacrimal bone, zygomatic bone, sphenoid bone, ethmoid process, vomer). It is a patient specific device. The implant is made of titanium alloy produced via Electron Beam Melting (EBM) additive manufacturing/3D printing, permitting high temperature fusion of the powdered raw material (Ti6Al4V ELI in accordance with ASTM F3001-14).

The BioArchitects plate implants come in a variety of configurations that depend upon the geometry of the application. The surgeon approves the design of the cranial/craniofacial plate by comparing his/her dimension and configuration specifications to an engineering drawing prior to construction of the implant device.

INDICATIONS FOR USE:
The BioArchitects Patient Specific Cranial/Craniofacial Plate implant device is intended to replace bony voids in the cranial and/or craniofacial skeleton (e.g., frontal bone, temporal bone, occipital bone, nasal bone, parietal bone, supraorbital process, lacrimal bone, zygomatic bone, sphenoid bone, ethmoid process, vomer). It is a patient specific device.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE:

Feature/ Characteristic	Subject Device	Synthes Patient Specific Cranial/Craniofacial Implant (PSCI)	Biomet HTR-PEKK Patient-Matched Implant	Medtronic TiMesh Pre-Shaped Cranial Mesh Implants
510(k)		K053199	K121818	K974017
Product Code(s)	GXN	GXN	GXN	GXN
Classification	Class II	Class II	Class II	Class II
Intended Use	The BioArchitects Patient Specific Cranial/Craniofacial Plate implant device is intended to replace bony voids in the cranial and/or craniofacial skeleton (e.g., frontal bone, temporal bone, occipital bone, nasal bone, parietal bone, supraorbital process, lacrimal bone, zygomatic bone, sphenoid bone, ethmoid process, vomer). It is a patient specific device.	Synthes (USA) Patient Specific Cranial/Craniofacial implant is intended to replace bony voids in the cranial and/or craniofacial skeleton.	The OsteoFAb Patient Specific Cranial Device (OPSCD) is intended for the replacement of bony voids in the cranial skeleton.	The TiMesh System is intended for use in any oral-maxilo-cranial-facial surgical reconstructive procedure, either orthnathic or trauma, wherein rigid or semi-rigid internal fixation is utilized as a means of holding bone fragments together. Alternatively, the TiMesh System is also indicated for use in reinforcing weak bony tissues in orthopedic surgical repairs, such as pelvic reconstruction, acetabular reconstruction, and cement restriction. This product is not intended for spinal use.
Material(s)	Titanium alloy	Commercially pure titanium or PEEK	PEKK	Titanium alloy
Technical Specifications	Custom sized to each patient using CT or MRI data	Custom sized to each patient using CT data	Custom sized to each patient using CT data	Custom sized to each patient using CT data
Manufacturing Method	3D printed using electron beam melting additive manufacturing	Machined	3D printed using laser sintering additive manufacturing	Machined
Fixation Method	Commercially available screw systems	Synthes plates and screw systems	Commercially available plate and screw systems	Medtronic plates, screws, and wires
Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile

Both the subject device and all predicates are the same in that they all derive the patient imaging data from CT scan sources. The material used for the subject device is the same as the reference predicate.

Both the subject device and the Medtronic reference predicate are constructed from titanium alloy, while the primary predicate has a different material, which may be either commercially pure titanium or PEEK (polyetheretherketone). The Biomet reference predicate is also manufactured from a material (PEKK, polyetherketoneketone) which is also different from the titanium alloy of the subject device.

The manufacturing technologies differ among the devices. The subject device is most closely similar to the Biomet reference predicate: Both utilize an additive 3D printing manufacturing technique, the Biomet device manufactured using laser sintering while the subject device uses electron beam melting (EBM), which is also a type of sintering process.

Both the primary predicate Synthes device and Medtronic predicate are fixed onto the bony surface using their own, captive screw and plate systems, while the subject device and the Biomet predicate utilize off-the-shelf commercially available screws.

Both the subject device and all predicates are the same in that devices are all shipped non-sterile to the end user.

PERFORMANCE DATA:

The BioArchitects Patient Specific Cranial/Craniofacial Plate was mechanically tested for tensile and elastic strength, with test results similar to those of predicate.

Performance Testing Summary Table

Test	Test Method Summary	Results
Cranial Plate Static Tensile Test	The objective of this test was to perform static tensile testing on sections of the BioArchitects Patient Specific Cranial/Craniofacial Plate device. Pate samples were cut into sections to prepare specimens for testing. For the test setup, the upper tensile grip was attached to the machine actuator using a U-joint. The lower tensile grip was attached to the axial bad eel. The plate specimen was gripped at both *ends,* leaving two holes exposed between the tensile grips. A nominal gage length of 30mm was used for each test specimen. Photographs of the tensile strength test setup are included in the Test Report.	The BioArchitects Patient Specific Cranial/Craniofacial plate device has an average ultimate stress of approximately 8 times that of the comparable device with the highest ultimate stress. Furthermore, the BioArchitects Patient Specific Cranial/Craniofacial Plate device has an average Young's modulus of approximately 3 times that of the comparable device with the highest Young's modulus. Results are presented in a side by side comparison table in the Test Report.
Cranial Plate Tab Static Tensile Test	The plate tab is the thinnest portion of the device, and therefore presents the worst case in terms of mechanical strength. The objective of this test was to perform a static tensile pull to failure test on the subject device compared to the predicate. For the test *method,* gage pins were placed through the screw hole in the attachment plate (tab) and the assembly placed in a gripping fixture. The test was conducted using a hydraulic actuator.	The BioArchitects Patient Specific Cranial/Craniofacial Plate device has an average tensile strength approximately 3.84 times that of the predicate fixation system. Specific results are presented in the test report.

CONCLUSIONS:

Based upon testing and comparison to the predicate device, the BioArchitects Patient Specific Cranial/Craniofacial Plate has the same intended use and similar technological characteristics. The device performs as intended and does not raise new safety or effectiveness issues.