August 26, 2022

MedCAD
% Linda Braddon, Ph.D.
CEO
Secure BioMed Evaluations
7828 Hickory Flat Highway, Suite 120
Woodstock, Georgia 30188

Re: K220357
Trade/Device Name: MedCAD AccuShape Titanium Patient-Specific Cranial Implant
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GXN
Dated: July 20, 2022
Received: July 20, 2022

Dear Dr. Linda Braddon:

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)*
K220357

Device Name
MedCAD AccuShape Titanium Patient-Specific Cranial Implant

Indications for Use *(Describe)*

The MedCAD AccuShape Titanium Patient-Specific Cranial Implant is designed individually for each patient and intended to correct defects / replace bony voids in the cranial skeleton.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) SUMMARY:

MedCAD® AccuShape® Titanium Patient-Specific Cranial Implant

Date Prepared	August 26, 2022
Sponsor Contact	MedCAD Brian Buss 501 S 2nd Ave, Suite A-1000 Dallas, TX 75226 (214) 453-8864 brian@medcad.com
510(k) Contact	Secure BioMed Evaluations Linda Braddon, Ph.D. 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 770-837-2681 Regulatory@SecureBME.com
Trade Name	MedCAD® AccuShape® Titanium Patient-Specific Cranial Implant
Common Name	Cranial Implant
Code – Classification	Classification Name: Preformed nonalterable cranioplasty plate (21 CFR 882.5330) Regulatory Class: II Product Code: GXN
Predicate Device	K110684 MedCAD® AccuShape® PEEK Patient Specific Cranial Implant
Reference Device	K053199 Synthes Patient Specific Cranial Implant K193280 MedCAD® AccuPlate® Patient-Specific Plate K192282 MedCAD® AccuPlan® System

Device Description	The MedCAD® AccuShape® Titanium Patient-Specific Cranial Implant is a preformed non-alterable cranioplasty plate that cannot be altered or reshaped at the time of surgery and is designed to be implanted in a patient to repair a skull defect. The subject device is composed of commercially pure (CP) Grade 2 titanium per ASTM F67. The manufacturing process is subtractive manufacturing (CNC milled) from models created and developed from patient specific CT Scan Data. The software used in this process is identical to the software used in the predicate device (K110684). The device is designed to have, as requested by the physician, drainage holes over the defect void area, fixation holes over an onlay area, and retractions and other features that fall within the approved design envelope. All designs must be approved by the physician prior to manufacture.
Indications for Use Statement	The MedCAD® AccuShape® Titanium Patient-Specific Cranial Implant is designed individually for each patient and intended to correct defects / replace bony voids in the cranial skeleton.

Comparison of Technological Characteristics

Characteristic	**Subject Device MedCAD® AccuShape® Titanium Patient-Specific Cranial Implant**	**Predicate Device MedCAD® AccuShape® PEEK Patient Specific Cranial Implant K110684**
Device Classification	Class II	Class II
Product Code	GXN	GXN
Indications for Use	The MedCAD® AccuShape® Titanium Patient-Specific Cranial Implant is designed individually for each patient and intended to correct defects / replace bony voids in the cranial skeleton.	The MedCAD® AccuShape® PEEK Patient Specific Cranial Implant is designed individually for each patient and intended to correct defects / replace bony voids in the cranial skeleton.
Material	Commercially pure (CP) titanium	PEEK
Design	Patient Specific Implant	Patient Specific Implant
Dimensions	Min: 10mm x 10mm Max: 200mm x 200mm	Min: 10mm x 10 mm Max: 200mm x 200mm

Characteristic	Subject Device MedCAD® AccuShape® Titanium Patient-Specific Cranial Implant	Predicate Device MedCAD® AccuShape® PEEK Patient Specific Cranial Implant K110684
Maximum Thickness	5mm	5mm
Attachment Method	Commercially available fixation systems	Commercially available fixation systems
Modifications	No Modifications allowed	No Modifications allowed
Non-Pyrogenic	Yes	Yes
Sterility	Provided non-sterile, to be steam sterilized	Provided non-sterile, to be steam sterilized
Biocompatibility	Implant device with permanent (>30 days) contact with tissue and bone	Implant device with permanent (>30 days) contact with tissue and bone

Technological Characteristics

There are no significant technological differences between the subject and predicate device. The subject device uses the same material as the reference device (K053199) and all devices are manufactured using subtractive techniques.

Non-Clinical Performance Testing Summary

Performance testing for the MedCAD® AccuShape® Titanium Patient-Specific Cranial Implant is summarized in the table below:

Test	Test Method Summary	Results
MR Compatibility Testing	Per ASTM F2503-20: Standard Practice For Marking Medical Devices And Other Items For Safety In The Magnetic Resonance Environment	The subject device was characterized to be **MR Unsafe**. This designation is noted in the labeling.
Screw Fixation Testing	Verification that fixation retention of the implant at the point of fixation of the screw is at least as strong as the axial pullout forces measured in prior testing of FDA-cleared neuro screws in an established cortical bone model.	**PASS** The fixation retention of the implant at the point of fixation of the screw is at least as strong as the axial pullout forces measured in prior testing of FDA-cleared neuro screws in an established cortical bone model.

Test	Test Method Summary	Results
Evaluation of Fit Testing	Subject devices using worst case CT data (1.25mm scan thickness) from 3 large defect predicate historical cases (K110684) with known CT scanners and configurations were used. The manufactured implant was optically scanned to verify alignment with the 3D model. Evaluation of fit was also validated by qualified inspectors by fitting the implant over the corresponding defect in a representative anatomical model.	**PASS** All samples met the predetermined acceptance criteria.
Comparative Strength	Identical subject and predicate devices (K110684 AccuShape PEEK) were used for testing. Pre-drilled fixation holes were placed at identical locations on all fixtures to ensure that all test samples were fixated at the same locations. All devices were applied to the same defect (same fit and fixation). A plunger was used to displace the center of each implant until failure. Load / displacement curves were collected.	**PASS** The subject device was substantially equivalent to the predicate device.

Conclusions

Based on the similarities of the intended use/indications for use, technological and functional characteristic, and the results of the non-clinical performance testing, the subject device is substantially equivalent to the legally marketed predicate device.