June 20, 2019

Dimensional Bioceramics, LLC
℅ Patsy Trisler
Regulatory Consultant
Trisler Consulting
5600 Wisconsin Ave, #509
Chevy Chase, Maryland 20815

Re: K182742
Trade/Device Name: DB-Cranial
Regulation Number: 21 CFR 882.5300
Regulation Name: Methyl Methacrylate for Cranioplasty
Regulatory Class: Class II
Product Code: GXP
Dated: May 20, 2019
Received: May 21, 2019

Dear Patsy Trisler:

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,

Matthew Krueger
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182742

Device Name
DB-Cranial

Indications for Use *(Describe)*
DB-Cranial is a calcium phosphate bone void filler indicated for the repair or filling of neurosurgical burr holes or other cranial bone defects and craniotomy cuts with a surface area no larger than 25 cm2. DB-Cranial may be used in the restoration or augmentation of bony contours of the cranial bone 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.

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510(k) Summary
DB-Cranial

I. SUBMITTER	
Submitter Name:	Dimensional Bioceramics, LLC
Submitter Address:	250 Natural Bridges Drive Santa Cruz, CA 95050
Contact Person: Telephone #:	Duran N. Yetkinler, M.D., Ph.D. 408-757-6603
Date Prepared:	May 6, 2019
II. DEVICE	
Device Trade Name:	DB-Cranial
Common or Usual Name:	Hydroxyapatite Cement
Regulatory Name(s):	Methyl Methacrylate For Cranioplasty
Classification #:	21 CFR 882.5300
Product Code:	GXP
III. PREDICATE DEVICE(s)	K162864, OsteoVation® Impact SkeletalKinetics , LLC
IV. DEVICE DESCRIPTION	
Device Identification, Characteristics, Sterilization and Shelf life	DB-Cranial Bone Void Filler is a moldable and biocompatible calcium phosphate bone void filler. DB-Cranial kit is comprised of two components: a calcium-phosphate powder and a mixing solution in premeasured quantities, which will be mixed together prior to implantation. The 3 cc, 5 cc, and 10 cc DB-Cranial Bone Void Filler kits are provided sterile to SAL of 10^{-6} and are for single use only. The sterilization method is gamma radiation. Sterilization validation is based on ISO 11137-2:2013 ($VD_{Max}25$). DB-Cranial Bone Void Filler will be labeled with a shelf life of 30 months.
V. INDICATIONS FOR USE	DB-Cranial is a calcium phosphate bone void filler indicated for repair or filling of neurosurgical burr holes, other cranial bone defects and craniotomy cuts with a surface area of no larger than $25cm^2$. DB-Cranial may be used in the restoration or augmentation of bony contours of the cranial bone skeleton.

VI. SUMMARY OF TESTING [PERFORMANCE DATA]		
Performance Bench Testing		
TEST	**Test Method Summary**	**Results**
Working Time In-Vitro	Ensures sufficient manipulation time is provided while also ensuring cement setting-times are met in the operative theater. Mixing, mold-ability, and setting strengths were measured	Both subject and predicate device reached sufficient indentation loads to ensure targeted working time and setting strength
Setting Time	Setting tests determined strength (Mean≥450N and ≥700N) at specified time points post sterilization and post mixing.	Subject and predicate devices achieved similar setting strengths at all time points. Strength values of these two setting cements are substantially equivalent.
Ca to P Ratio	This test determines CA/P ratios via ICP-MS.	Both samples have a Ca/P ratio of 1.5. This test confirms both subject and predicate are composed of identical amounts of calcium and phosphate salts.
Kit Components	Kit ingredients are compared to determine substantial equivalence.	Both subject and predicate device consist of alpha-tricalcium phosphate (Powder) and sodium silicate-sodium phosphate solution (Liquid).
Heavy Metal Analysis	Samples are analyzed for trace heavy metal content using ICP-MS.	Trace metal limits were below allowable limits in both subject and predicate.
pH Profile	Examines effects of the device on pH surrounding the implanted device. pH is measured in physiologic buffer solutions surrounding curing cements.	All pH readings remained within normal physiological range for both predicate and subject devices.
FTIR Analysis	This test identifies the chemical composition of subject and predicate device following curing in simulated physiologic conditions for 24 hours then dry cured at 37°C for 72 hours.	Both subject and predicate device both show the formation of hydroxyapatite. Subject and predicate device are substantially equivalent with regards to FTIR chemical analysis.

Crystallographic Analysis	XRD analysis is performed with samples set in simulated physiologic conditions for 2 hours, 1 day, 3 days, and 7 days. Samples are evaluated using powder x-ray diffraction and compared against known mineralogic standards.	Both subject and predicate device are confirmed identical via crystallographic analysis. The same crystalline structure over several different clinically relevant time points is formed in both materials.
Temperature Profile	Device samples are tested in simulated physiologic solutions to measure temperature of curing cement. Temperatures above, at, and below the level of the sample are measured at 2 minute intervals over 20 minutes.	Both subject and predicate device set in an isothermic manner as designed. This demonstrates a minimal risk of thermal necrosis of tissue surrounding the implantation site. In this respect, both subject and predicate device are substantially equivalent.
Solubility and Dissolution	Test samples are cured and incubated at simulated physiological conditions for 4 days; fluid is extracted and tested for Ca^{2+} concentration via ICP-AES. This experiment evaluates solubility and dissolution.	Both subject and predicate device have substantially equivalent solubility and dissolution.
Tensile Testing	Test samples were mixed and cured for 24 hours at simulated temperature and pH. Tensile testing was performed using a mechanical tester and load at sample breakage was recorded and compared.	Subject and predicate device demonstrated identical tensile strength at 24 hours and are substantially equivalent in terms of tensile strength.
Dimensional Stability	Dimensional stability is measured to establish that the bone void fillers maintain shape and do not dissolve in an untimely manner.	Subject and predicate are dimensionally stable materials with no discernable differences in form.
Physical Form	Test samples were imaged by SEM to determine microstructural similarities and differences.	Both subject and predicate device demonstrated hydroxyapatite crystal formation. Subject and predicate device set to form hydroxyapatite in an identical manner.
Biocompatibility Testing:	No biocompatibility studies were needed to demonstrate substantial equivalence.	

Animal Testing:	No animal studies were needed to demonstrate substantial equivalence.	
Clinical Testing:	This product type does not require clinical testing.	
VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE		DB-Cranial intended use and critical specifications are substantially equivalent to the predicate device, OsteoVation Impact® (K162864), as shown by the comparative testing. There are no notable differences in comparison to the predicate device, therefore no new questions related to safety and effectiveness were raised.
VII. CONCLUSIONS		Based on the comparison provided and the data submitted in the 510(k), it can be concluded the DB- Cranial is substantially equivalent to the predicate device, OsteoVation Impact® (K162864).