March 15, 2021

Dimensional Bioceramics, LLC
℅ Patsy Trisler
Regulatory Consultant
Trisler Consulting
7949 Beaumont Green East Drive
Indianapolis, Indiana 46250

Re: K210193
Trade/Device Name: DB-Composite Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: January 19, 2021
Received: January 25, 2021

Dear Ms. 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,

for

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic 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)*
K210193

Device Name

DB-Composite

Indications for Use *(Describe)*

DB-Composite Bone Void Filler is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, posterolateral spine, pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. DB-Composite is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.

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.

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K210193

Section 5

510(k) Summary

I. SUBMITTER

Submitter Name	Dimensional Bioceramics, LLC
Submitter Address	2161 Delaware Avenue, Suite A Santa Cruz, CA 95060
Contact Person	Duran N. Yetkinler, M.D., Ph.D.
Phone Number	408-757-6603
Date Prepared	March 12, 2021

II. DEVICE

Trade Name	DB-Composite Bone Void Filler
Common Name	Bone Void Filler
Classification	Resorbable Calcium Salt Bone Void Filler Device
Name Number	21 CFR 888.3045
Product Code	MQV
Regulatory Class	Class 2

III. PREDICATE AND REFERENCE DEVICES

Predicate Device	K112383, Skeletal Kinetics, Callos ProModel Bone Void Filler
Reference Device	K182742, Dimensional Bioceramics, DB-Cranial

IV. INDICATIONS FOR USE

This submission has identical indications for use as the predicate device.

Indications For Use Statement	DB-Composite Bone Void Filler is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, posterolateral spine, pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. DB-Composite is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.

V. DEVICE DESCRIPTION

Device Identification DB-Composite Bone Void Filler is a moldable and biocompatible calcium sulfate/calcium phosphate bone void filler. The DB-Composite kit is comprised of two components: A calcium sulfate/calcium phosphate powder mix and a mixing solution in premeasured quantities, which will be mixed together prior to implantation.

Technological Characteristics The 3cc, 5cc, and 10cc DB-Composite Bone Void Filler Kits are provided sterile to SAL 10^{-6} and are for single use only.

VI. PERFORMANCE TESTING

Test Method Summary: The following testing was performed on the predicate device and presented in the documentation in K112383.

Test	Test Method Summary
Working Time In Vitro	Ensures sufficient manipulation time is provided while also ensuring setting times are met it the operative theater.
Setting Time	Measures the time for a bone void filler to set in simulated physiologic conditions.
Heavy Metal Analysis	Samples are analyzed for trace heavy metal content using ICP-MS according to ASTM F1185-03.
pH Profile	Examines effects of the device on pH surrounding the implanted device. pH is measured in physiologic buffer solution proximal to curing cement.
FTIR Analysis	This test identifies the chemical composition of subject and predicate device following curing in simulated physiologic conditions.
Crystallographic Analysis	XRD analysis is performed with samples set in simulated physiologic conditions for specified times and evaluated using powder x-ray diffraction and compared against known mineralogic standards.
Temperature Profile	Device samples are tested in simulated physiologic solution to measure temperature of curing cement.
Solubility and Dissolution	Test samples are cured and incubated at simulated physiological conditions for a specified time and measured for solubility and dissolution.

Test	Test Method Summary
Tensile Testing	Test samples were mixed and cured for 24 hours at simulated physiological conditions for a specified time and measured for solubility and dissolution.
Dimensional Stability	Dimensional stability is measured to establish that the bone void fillers maintain shape and do not dissolve in an untimely manner.
Physical Form	Test samples were imaged by SEM to determine microstructure. Testing confirmed hydroxyapatite and calcium sulfate dihydrate crystal formation.
Biocompatibility	No new biocompatibility studies were needed to demonstrate substantial equivalence. No changes to the product were made from the identical predicate device.
Sterilization and Shelf Life	The product is sterilized by gamma radiation to a SAL of 10^{-6} and validated according to ANSI/AAMI/ISO 11137:1995.
Bacterial Endotoxins	Testing, according to USP<85> and USP<161>, showed the product meets the acceptance limit of 20 EU/device.
Animal Testing	No new animal studies were needed to demonstrate substantial equivalence, since the device is identical to the predicate device.
Clinical Testing	This product category does not require human clinical testing.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

DB-Composite Bone Void Filler's intended use and critical specifications are substantially equivalent to the predicate device, Skeletal Kinetics Callos ProModel Bone Void Filler.

Further, this product is composed of the identical materials, and is manufactured and packaged by the same processes and core staff members as the predicate device. The only difference is the subject device is manufactured in a different facility than the predicate device; but the manufacturing location for the Reference device is the same as the subject, DB-Composite, device.

There are no notable differences in comparison to the predicate device, therefore no questions related to safety and efficacy were raised.

VIII. CONCLUSIONS

Based on the comparisons shown and the information provided in this 510(k), it can be concluded that DB-Composite is substantially equivalent to the predicate device Skeletal Kinetics Callos ProModel.