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

April 22, 2020

Re: K200752
Trade/Device Name: DB-Orthopedics
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: March 17, 2020
Received: March 23, 2020

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,

Jesse Muir, Ph.D.
Acting 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)*
K200752

Device Name

DB-Orthopedics

Indications for Use *(Describe)*

DB-Orthopedics Bone Void Filler is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, spine, pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. DB-Orthopedics 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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510(k) Summary – K200752

I. SUBMITTER

Submitter Name:	Dimensional Bioceramics, LLC
Submitter Address:	2161 Delaware Ave., Suite A Santa Cruz, CA 95060
Contact Person:	Duran N. Yetkinler, M.D., Ph.D.
Phone Number:	408-757-6603
Date Prepared:	March 17, 2020

II. DEVICE

Trade Name:	DB-Orthopedics Bone Void Filler
Common Name	Bone Void Filler
Classification Name Number	Resorbable calcium salt bone void filler device 21 CFR 888.3045
Product Code	MQV
Regulatory Class	Class 2

III. PREDICATE DEVICE

Primary Predicate Device:	K051123, Callos™ Bone Void Filler, Skeletal Kinetics
Reference Device:	K182742, DB-Cranial Bone Void Filler, Dimensional Bioceramics, LLC

IV. INDICATIONS FOR USE

This submission expands the indications for use of the DB-Cranial 510(k) (Reference Device K182742) clearance to orthopedics.

Indications for Use Statement	DB-Orthopedics Bone Void Filler is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, spine, pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. DB-Orthopedics 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-Orthopedics Bone Void Filler is a moldable, injectable and biocompatible calcium phosphate bone void filler. The DB-Orthopedics 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.
Technological Characteristics	The 3 cc, 5 cc, and 10 cc DB-Orthopedics Bone Void Filler kits are provided sterile to SAL of 10^{-6} and are for single use only.

VI. PERFORMANCE TESTING	
Test	**Test Method Summary**
Working Time In Vitro	Ensures sufficient manipulation time is provided while also ensuring cement setting-times are met in the operative theater.
Setting Time	This test measures the time for a bone void filler to set in simulated physiologic conditions.
Ca to P Ratio	This test determines CA/P ratios via ICP-MS. DB-Orthopedics has a ratio of 1.5.
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 solutions surrounding curing cements.
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 solutions 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.
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.
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 crystal formation.
Biocompatibility	No biocompatibility studies were needed to demonstrate substantial equivalence. No changes to the product were made from the original submission.
Pyrogenicity	Pyrogenicity (LAL) testing is routinely performed on the product.
Sterilization and Shelf Life	The sterilization method is gamma radiation. Sterilization validation is based on ISO 11137-2:2013 ($VDMax_{25}$). DB-Orthopedics Bone Void Filler will be labeled with a shelf life of 30 months.

Animal Testing	No animal studies were needed to demonstration substantial equivalence.
Clinical Testing	This product category does not require human clinical testing.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

DB-Orthopedics Bone Void Filler's intended use and critical specifications are identical to the predicate device, Skeletal Kinetics' Callos™ Bone Void Filler, K051123.

Further, this product is composed of the identical material, and is manufactured and packaged by the identical processes and in the identical facility, as the recently cleared Reference Device, K182742.

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

VIII. CONCLUSIONS

Based on the comparisons provided and the data submitted in this 510(k), it can be concluded the DB-Orthopedics is substantially equivalence to Callos™ predicate device.