Dimensional Bioceramics™ LLC
℅ Patsy J. Trisler, JD, RAC
Regulatory Consultant
Trisler Consulting
5600 Wisconsin Avenue #509
Chevy Chase, Maryland 20815

Re: K171161
Trade/Device Name: Dimensional Bioceramics Calcium Sulfate Device (DB-CSD)
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: August 14, 2017
Received: August 17, 2017

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. 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 (DICE) 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 (DICE) 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,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Indications for Use

Device Name
Dimensional Bioceramics Calcium Sulfate Device (DB-CSD)

Indications for Use (Describe)

Dimensional Bioceramics™ (DB) Calcium Sulfate Device (CSD) is a bone graft substitute that is intended for use as a bone void filler for voids and gaps and pelvis that are not intrinsic to the stability of the bony structure. These osseous defects may be surgically created or created from a traumatic injury to the bone. DB-CSD is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., extremities and pelvis). DB-CSD is a bone graft substitute that resorbs and replaced with bone during the healing process. DB-CSD is biodegradable and biocompatible and may be used in an infected site.

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

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
### I. SUBMITTER

<table>
<thead>
<tr>
<th>Submitter Name:</th>
<th>Dimensional Bioceramics™ LLC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submitter Address:</td>
<td>163 McKenzie Creek Road Scotts Valley, CA 95066</td>
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<td>Contact Person:</td>
<td>David Delaney, Director</td>
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<td>Telephone #:</td>
<td>831.234.4892</td>
</tr>
<tr>
<td>Date Prepared:</td>
<td>August 14, 2017</td>
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</tbody>
</table>

### II. DEVICE

<table>
<thead>
<tr>
<th>Device Trade Name:</th>
<th>Dimensional Bioceramics Calcium Sulfate Device (DB-CSD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory Name(s):</td>
<td>Resorbable Calcium Sulfate Bone Void Filler</td>
</tr>
<tr>
<td>Classification #:</td>
<td>21 CFR 888.3045</td>
</tr>
<tr>
<td>Product Code:</td>
<td>MQV</td>
</tr>
</tbody>
</table>

### III. PREDICATE DEVICE(s)

| K141830, Stimulan Rapid Cure, Biocomposites, Ltd. |

### IV. DEVICE DESCRIPTION

<table>
<thead>
<tr>
<th>Device Identification, Characteristics, Mechanism of Action:</th>
<th>Dimensional Bioceramics (DB) Calcium Sulfate Device (CSD) [DB-CSD] Bone Void Filler Kit is provided sterile for single patient use. The Kit contains medical grade calcium sulfate powder and mixing solution in pre-measured quantities. When mixed together in a sterile mixing bowl, the resultant paste may be injected, digitally implanted, or applied to a mold to produce pellets. DB-CSD resorbs and is replaced with bone during the healing process. DB-CSD is a moldable, biocompatible, biodegradable, and resorbable calcium sulfate material that is to be applied directly to the intended sites. It may be used within an infected site. The critical specifications are chemistry, crystallinity, physical form, porosity, and solubility.</th>
</tr>
</thead>
</table>
### V. INDICATIONS FOR USE

Dimensional Bioceramics™ (DB) Calcium Sulfate Device (CSD) is a bone graft substitute that is intended for use as a bone void filler for voids and gaps and pelvis that are not intrinsic to the stability of the bony structure. These osseous defects may be surgically created or created from a traumatic injury to the bone. DB-CSD is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., extremities and pelvis). DB-CSD is a bone graft substitute that resorsbs and replaced with bone during the healing process. DB-CSD is biodegradable and biocompatible and may be used in an infected site.

### VI. SUMMARY OF TESTING [PERFORMANCE DATA]

Performance, Safety and Biocompatibility test data are provided in the 510(k) application. They include the following:

| Laboratory Testing | Critical specifications (chemistry, crystallinity, physical form, porosity, and solubility) of DB-CSD were compared with those of the predicate device. Chemistry was determined by Fourier Transformed Infrared Spectroscopy (FTIR) and X-ray Diffraction (XRD) techniques. Crystallinity was determined by X-ray Diffraction. Physical form was determined by Scanning Electron Microscopy. Porosity was determined by Mercury Intrusion Porosimetry. Solubility was measured by in vitro dissolution method measuring Ca$^{2+}$ ion concentration in solution using Inductively Coupled Plasma – Atomic Emission Spectroscopy. |
| Biocompatibility Testing | Biocompatibility tests, according to ISO 10993-1 were performed and are provided in the 510(k) documentation. They demonstrated DB-CSD met the requirements of the ISO standards. |
| Pyrogenicity Testing | ISO Materials Mediated Rabbit Pyrogen testing was performed and provided in the 510(k). The results of the testing indicate the DB-CSD is non-pyrogenic. |
| Sterilization and Shelf-Life Testing | DB-CSD will be provided as a single use, sterile medical device. The radiation dose of 25k Gy-40 kGy has been validated in accordance with ISO 11137-2006, Sterilization of Health Care Products - Radiation to Sterility Assurance Level (SAL) $10^{-6}$. |
| Animal Testing | An animal study was performed to analyze the biocompatibility, implant resorption, bone formation, and surgical handling properties following metaphyseal implantation in an ovine, critical size, cancellous bone defect model. No abnormal acute hematologic and major organ toxicity was observed in both subject and predicate devices. Histological and radiographic data demonstrated that both materials appeared to be |
biocompatible, and complete resorption of the implanted regions, followed by normal bone healing occurred for both subject and predicate devices by 12 weeks.

| Clinical Testing: | N/A: This product type does not require clinical testing. |

| VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE | DB-CSD intended use and critical specifications are substantially equivalent to the predicate device, Stimulan Rapid Cure of Biocomposites Ltd (K141830). Both medical devices are composed of a hydrated calcium sulfate salt that is implanted following mixing with a solution component that yields 5, 10, or 20 cc. Performance test results demonstrated that DB-CSD has substantially equivalent critical specifications (chemistry, crystallinity, physical form, porosity, and solubility) as the predicate device, Stimulan Bone Void Filler. |

| VIII. CONCLUSIONS | Based on the comparison provided and the data submitted in the 510(k), it can be concluded the DB-CSD is substantially equivalent to the predicate device, Stimulan - Rapid Cure Bone Void Filler (K141830). |