March 21, 2023

DSM Biomedical
Diana Osgood
Senior Regulatory Affairs Specialist
735 Pennsylvania Drive
Exton, Pennsylvania 19431

Re: K230054
Trade/Device Name: DSM Biomedical Calcium Phosphate Cement
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV, OIS,
Dated: January 6, 2023
Received: January 6, 2023

Dear Ms. Diana Osgood:

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,

Sara S. Thompson -S

For

Laurence D. Coyne, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230054

Device Name
DSM Biomedical Calcium Phosphate Cement

Indications for Use *(Describe)*
DSM Biomedical Calcium Phosphate Cement is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities and pelvis). These defects may be surgically created, or osseous defects created from traumatic injury to the bone. The Calcium Phosphate Cement is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The Calcium Phosphate Cement cured in situ provides an open void/gap filler that can augment provisional hardware (e.g. K-Wires, plates, screws) to help support bone fragments during the surgical procedure. The cured cement acts only as a temporary support media and is not intended to provide structural support during the healing process. The Calcium Phosphate Cement 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

I. SUBMITTER

Submitter:	DSM Biomedical 735 Pennsylvania Drive Exton, PA 19341
Phone:	484-713-2100
Contact Person:	Diana Osgood
Date Prepared:	March 14, 2023

II. DEVICE

Trade Name:	**DSM Biomedical Calcium Phosphate Cement**
Common/Usual Name:	Bone Void Filler
Classification Name:	Resorbable Calcium Salt Bone Void Filler Device
Classification Regulation:	21 CFR 880.3045
Device Class:	2
Device Code:	MQV: Filler, Bone Void, Calcium Compound OIS: Calcium Salt Bone Void Filler, Drillable, Non-screw Augmentation
Advisory Panel:	Orthopedic

III. PREDICATE DEVICE

Substantial equivalence is claimed to the following device:

- DSM Biomedical Calcium Phosphate Cement, K173362

IV. DEVICE DESCRIPTION

The DSM Calcium Phosphate Cement is a line extension to the current DSM Calcium Phosphate Cement product line, which introduces the 1cc size and a new packaging configuration. DSM Calcium Phosphate Cement is an injectable, sculptable, drillable, fast self-setting bone substitute. DSM Calcium Phosphate Cement is composed of calcium phosphate, which converts to hydroxyapatite in vivo, and bovine collagen powder. The device can also be used to augment provisional hardware to help support bone fragments during the surgical procedure. The cement is provided in a powder form and is packaged in a female luer syringe. An empty male luer syringe is provided to allow for syringe-to-syringe mixing of the powder with saline at the required powder-to-liquid ratio. DSM Calcium Phosphate Cement is supplied sterile by gamma irradiation and is non-pyrogenic.

V. INDICATIONS FOR USE:

DSM Biomedical Calcium Phosphate Cement is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities and pelvis). These defects may be surgically created, or osseous defects created from traumatic injury to the bone. The Calcium Phosphate Cement is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The Calcium Phosphate Cement cured in situ provides an open void/gap filler that can augment provisional hardware (e.g. K-Wires, plates, screws) to help support bone fragments during the surgical procedure. The cured cement acts only as a temporary support media and is not intended to provide structural support during the healing process. The Calcium Phosphate Cement resorbs and is replaced by bone during the healing process.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERSTICS WITH THE PREDICATE DEVICE

The DSM Calcium Phosphate Cement is a line extension of the currently cleared 5cc DSM CPC (predicate device, K173362). The 1cc device maintains the same formulation and indication for use as the 5cc device but will be packaged in a different configuration. The subject device is substantially

equivalent in terms of indications for use, material composition, technological characteristics, and performance characteristics to the predicate device. The devices are compared in the table below.

Characteristic	1cc DSM Biomedical Calcium Phosphate Cement (*Subject Device*)	DSM Biomedical Calcium Phosphate Cement (K173362 *Predicate Device*)
Indications for Use	DSM Biomedical Calcium Phosphate Cement is indicated to fill bony voids or gaps of the skeletal system (i.e., extremities and pelvis). These defects may be surgically created, or osseous defects created from traumatic injury to the bone. The Calcium Phosphate Cement is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The Calcium Phosphate Cement cured in situ provides an open void/gap filler that can augment provisional hardware (e.g., K-Wires, plates, screws) to help support bone fragments during the surgical procedure. The cured cement acts only as a temporary support media and is not intended to provide structural support during the healing process. The Calcium Phosphate Cement resorbs and is replaced by bone during the healing process.	DSM Biomedical Calcium Phosphate Cement is indicated to fill bony voids or gaps of the skeletal system (i.e., extremities and pelvis). These defects may be surgically created, or osseous defects created from traumatic injury to the bone. The Calcium Phosphate Cement is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The Calcium Phosphate Cement cured in situ provides an open void/gap filler that can augment provisional hardware (e.g., K-Wires, plates, screws) to help support bone fragments during the surgical procedure. The cured cement acts only as a temporary support media and is not intended to provide structural support during the healing process. The Calcium Phosphate Cement resorbs and is replaced by bone during the healing process.
Material	Calcium phosphate powder with bovine collagen mixed with saline to form hydroxyapatite	Calcium phosphate powder with bovine collagen mixed with saline, patient's blood, or patient's bone marrow aspirate to form hydroxyapatite
Form	Injectable, sculptable, drillable, and fast setting calcium phosphate cement that converts to hydroxyapatite	Injectable, sculptable, drillable, and fast setting calcium phosphate cement that converts to hydroxyapatite
Packaging	Powder pre-packaged in a female luer syringe, packaged with accessories to	Powder prepackaged in a mixing and delivery syringe, packaged with

Characteristic	1cc DSM Biomedical Calcium Phosphate Cement (*Subject Device*)	DSM Biomedical Calcium Phosphate Cement (K173362 *Predicate Device*)
	aid in the mixing and delivery of cement	accessories to aid in the mixing and delivery of cement
Sterilization	Sterile by gamma irradiation	Sterile by gamma irradiation
Reusable	Single Use Device	Single Use Device
Biocompatible	Yes	Yes
Sizes Offered	1cc	5cc

The DSM Calcium Phosphate Cement is a line extension to the current DSM CPC product line, which introduces the 1cc size and a new packaging configuration. DSM Biomedical Calcium Phosphate Cement and the predicate device have identical indications for use and are for use in the same target population. The subject and predicate devices are composed of the same materials and are the delivered in the same form. Both are sterilized by gamma irradiation and are for single use only. The additional size and new packaging of the subject device does not raise questions of substantial equivalence as verification testing confirms that the subject device meets the established design requirements.

VII. SUMMARY OF NON-CLINICAL TESTING TO SUPPORT SUBSTANTIAL EQUIVALENCE

The following performance data was provided in support of the substantial equivalence determination.

Mechanical and Physical Testing

Material characterization and performance testing of the DSM Biomedical Calcium Phosphate Cement was completed in accordance with the FDA Guidance Document, *Resorbable Calcium Salt Bone Void Filler Device* and ***ASTM F1185*** *Standard Specification for Composition of*

Hydroxylapatite for Surgical Implants. Bench testing included product appearance, handling, injectability, setting time, compressive strength, X-ray diffraction, porosity, and anchor pull out strength.

The Bacterial Endotoxins Test (BET) was conducted on the finished device to detect and quantify the presence of bacterial endotoxins using the gel-clot method. The device met endotoxin limit specifications according to FDA-recognized standards USP <85> *Bacterial Endotoxins Test and* AAMI ANSI ST72: 2019 *Bacterial Endotoxins - Test methodologies, routine monitoring, and alternative to batch testing*. The endotoxin limit is not more than 20 Endotoxin Units per device.

The packaging of the subject device was designed to meet the requirements of ISO 11607-1. The subject device is gamma sterilized and has been validated per ISO 11137-1 and ISO 11137-2. Stability testing on the device was performed and confirms the shelf life of the subject device.

Biocompatibility Testing

Biocompatibility testing was completed in accordance with the requirements of *ISO 10993-1: 2018, Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing within a Risk Management Process* for a permanent implant device with tissue/bone contact. Testing included the following biological effects:

- Cytotoxicity per ISO 10993-5
- Sensitization per ISO 10993-10
- Irritation per ISO 10993-10
- Acute Systemic Toxicity per ISO 10993-11
- Genotoxicity per ISO 10993-3
- Subacute Systemic Toxicity per ISO 10993-3

Pyrogenicity testing per USP<85> and Rabbit Material Mediated Pyrogenicity per ISO 10993-11 have been completed to verify that the device is non-pyrogenic.

The bovine collagen is sourced in accordance with ISO 22442-2 and per FDA Guidance Document, *Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices).*

Viral inactivation studies per ISO 22442-3 and a residual chemical assessment per ISO 10993-17 were conducted.

Results indicate that the device's biocompatibility profile is acceptable.

Performance Animal Testing

The performance of DSM Biomedical Calcium Phosphate Cement plus saline (DSM + Saline) was compared to Stryker Hydroset in an ovine critical sized femoral defect model. At the 12-week timepoint, animal study data demonstrated new bone formation averages of 5.8% ±-2% in the DSM + saline group, 6.3% ±-3.2% in the Hydroset predicate group, and 24.3% ±-7.3% in the empty defect negative control group. Animal study data demonstrated that approximately 84.2% of implant material remained in the DSM + saline group, and 86.6% remained in the Hydroset predicate group 12 weeks following implantation. Clinical performance has not been evaluated.

VIII. CONCLUSIONS

Pursuant to section 510(k), DSM Biomedical Calcium Phosphate Cement is substantially equivalent to the predicate device DSM Biomedical Calcium Phosphate Cement with regard to indication for use, technological characteristics (including principles of operation), and performance characteristics.