



Kensey Nash Corporation dba DSM Biomedical
Susan Pileggi
Senior Regulatory Specialist
735 Pennsylvania Drive
Exton, Pennsylvania 19431

April 3, 2018

Re: K173362

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: February 26, 2018
Received: February 28, 2018

Dear Ms. Pileggi:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K173362

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 DSM Biomedical Calcium Phosphate Cement is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The DSM Biomedical 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.

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510(k) Summary

Submitted By: DSM Biomedical
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Contact Person: Susan Pileggi
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Date Prepared: February 23, 2018

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: II
Device Code: MQV: Filler, Bone Void, Calcium Compound
OIS: Calcium Salt Bone Void Filler, Drillable, Non-screw Augmentation
Advisory Panel: Orthopedic

Predicate Device: Stryker® Injectable Cement (K060061) [Stryker® CMF]

Device Description

DSM Biomedical Calcium Phosphate Cement as an injectable, sculptable, fast self-setting bone substitute. DSM Biomedical 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 packaged in a mixing syringe. The mixing syringe allows for the combination of saline, the patient's blood, or the patient's bone marrow at the required powder-to-liquid ratio. DSM Biomedical Calcium Phosphate Cement is supplied sterile by gamma irradiation and is non-pyrogenic.



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.

Basis for Substantial Equivalence:

The DSM Biomedical Calcium Phosphate Cement is substantially equivalent in terms of indications for use, material composition, technological characteristics and performance characteristics to that of the predicate device, Stryker® Injectable Cement (K060061).

DSM Biomedical Calcium Phosphate Cement and the predicate device have comparable indications for use. Both are calcium phosphate powders that when mixed with a mixing liquid form a fast setting cement. The addition of the collagen to the subject device does not raise questions of substantial equivalence as the safety of the collagen has been shown through biocompatibility, an animal study, and a viral inactivation study. The subject and predicate devices are both injectable, sculptable, and fast setting calcium phosphate cement that converts to hydroxyapatite over time. Both the subject and predicate devices are packaged with accessories to aid in the mixing and delivery of the cement. The subject and predicate devices are provided sterile and are for single use only. The subject and predicate devices are biocompatible and non-pyrogenic.



Characteristic	DSM Biomedical Calcium Phosphate Cement (Proposed)	Stryker® Injectable Cement (K060061)
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 <i>in situ</i> 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.	Stryker Injectable Cement is a self-setting calcium phosphate cement indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, craniofacial, spine, and pelvis.) These defects may be surgically created or osseous defects created from traumatic injury to the bone. The Stryker Injectable Cement is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Stryker Injectable Cement cured <i>in situ</i> 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.
Material	Calcium phosphate powder with bovine collagen mixed with saline, patient's blood, or patient's bone marrow to form hydroxyapatite	Calcium phosphate powder mixed with mixing liquid to form hydroxyapatite
Form	Injectable, sculptable, and fast setting calcium phosphate cement that converts to hydroxyapatite	Injectable, sculptable, and fast setting calcium phosphate cement that converts to hydroxyapatite
Packaging	Powder prepackaged in a mixing and delivery syringe, packaged with accessories to aid in the mixing and delivery of cement	Calcium phosphate powder in a bowl, packaged with accessories to aid in the mixing and delivery of the cement
Sterilization	Sterile, SAL 10 ⁻⁶	Sterile, SAL 10 ⁻⁶
Reusable	Single Use Device	Single Use Device
Biocompatible	Yes	Yes

Performance Data:

Material characterization, including chemical and material physical characterization, bench testing, biocompatibility testing, viral inactivation, and an animal study have been conducted to evaluate the performance characteristics and biological safety of DSM Biomedical Calcium Phosphate Cement.



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*.

An ovine bilateral femoral defect animal study was performed to evaluate bone healing following treatment with the DSM Biomedical Calcium Phosphate Cement compared to the predicate device.

Biocompatibility testing was completed in accordance with the requirements of *ISO 10993-1: 2009, 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 cytotoxicity, sensitization, irritation, acute systemic toxicity, genotoxicity, hemocompatibility, subacute toxicity, chronic toxicity, and implantation. Other safety testing included a viral inactivation study and residual chemical assessment. Results indicate that the device's biocompatibility profile is acceptable.

Substantial Equivalence:

DSM Biomedical Calcium Phosphate Cement has the same intended use and similar indications, technological characteristics, and principles of operation as the predicate device. The minor technological differences that exist between the DSM Biomedical Calcium Phosphate Cement do not raise any new issues of safety and effectiveness. The bench, animal, and biocompatibility testing demonstrates that DSM Biomedical Calcium Phosphate Cement is substantially equivalent to the predicate device.

Conclusion:

The DSM Biomedical Calcium Phosphate Cement is substantially equivalent in terms of indications for use, material composition, technological characteristics, and performance characteristics to the predicate device, Stryker® Injectable Cement (K060061) [Stryker® CMF].