April 11, 2018

Cellumed Co., Ltd.
% Justin Eggleton
Senior Director, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K180121
Trade/Device Name: Rafugen™ DBM
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: January 12, 2018
Received: January 16, 2018

Dear Mr. Eggleton:

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K180121

Device Name
Rafugen™ DBM

Indications for Use *(Describe)*
Rafugen DBM is intended for use as a bone void filler in bony voids or gaps of the skeletal system (i.e., pelvis and extremities) not intrinsic to the stability of the bony structure. The voids or gaps may be surgically created defects or defects created by traumatic injury to the bone. Rafugen DBM is resorbed/remodeled and is replaced by host 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 (K180121)

for

Rafugen™ DBM

1. Submission Sponsor

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2. Submission Correspondent

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3. Date Prepared

April 4, 2018

4. Device Identification

Trade/Proprietary Name:	Rafugen™ DBM
Common/Usual Name:	Resorbable bone void filler containing demineralized bone
Classification Name:	Resorbable calcium salt bone void filler device
Classification Regulation:	21 CFR §888.3045
Product Code:	MBP, MQV
Device Class:	Class II
Classification Panel:	Orthopedic

5. Legally Marketed Predicate Device(s)

GRAFTON® DBM, K051195

6. Device Description

Rafugen™ DBM is a human bone allograft product containing human DBM (demineralized bone matrix), CMC (carboxymethyl cellulose), Starch and Glycerol. It is intended for use in

filling bony voids or gaps of the skeletal system not intrinsic to the stability of the bony structure. Rafugen™ DBM is a ready-to use moldable gel formulation provided pre-filled in syringes of various volumes and is intended for single patient use. It is offered in six volumes: 0.25, 0.5, 1.0, 3.0, 5.0, and 10.0 cc. The Rafugen™ DBM can be either directly applied into the defect from the syringe, using the cap tip, or extruded for molding and insertion into the defect by hand.

Rafugen™ DBM is packaged in a double foil pouch and sealed within a PE pouch prior to placement into a paperboard carton.

7. Indication for Use Statement

Rafugen™ DBM is intended for use as a bone void filler in bony voids or gaps of the skeletal system (i.e., pelvis and extremities) not intrinsic to the stability of the bony structure. The voids or gaps may be surgically created defects or defects created by traumatic injury to the bone. Rafugen™ DBM is resorbed/remodeled and is replaced by host bone during the healing process.

8. Substantial Equivalence Discussion

The following table compares the Rafugen™ DBM to the predicate device with respect to intended use, technological characteristics and performance.

Table 5A – Comparison of Characteristics

	Rafugen™ DBM	**GRAFTON® DBM K051195**	**Comparison**
Manufacturer	Cellumed Co., Ltd.	Osteotech Inc.	N/A
Classification Number	21 CFR §888.3045 (Resorbable calcium salt bone void filer device)	21 CFR §888.3045 (Resorbable calcium salt bone void filer device)	Same
Classification Product Code	MBP, MQV	MBP, MQV	Same
Indications for Use	Rafugen™ DBM is intended for use as a bone void filler in bony voids or gaps of the skeletal system (i.e., pelvis and extremities) not intrinsic to the stability of the bony structure. The voids or gaps may be surgically created defects or defects created by traumatic injury to the bone. Rafugen™ DBM is resorbed/remodeled and is replaced by host bone during the healing process.	GRAFTON® DBM is intended for use as a bone graft extender, bone graft substitute, and bone void filler in bony voids or gaps of the skeletal system (i.e., spine, pelvis and extremities) not intrinsic to the stability of the bony structure. The voids or gaps may be surgically created defects or defects created by traumatic injury to the bone. GRAFTON® DBM is resorbed/remodeled and is replaced by host bone during the healing process.	Similar – GRAFTON® is also indicated for use as a bone graft extender and for use in the posterolateral spine, whereas Cellumed is not seeking those indications for Rafugen™ DBM
Main Material	DBM, human cortical bone powder	DBM, human cortical bone powder	Same

Sub Material (Carrier)	CMC, Starch and Glycerol	Glycerol	Same for glycerol. (CMC and starch are additional carrier materials to control the viscosity with glycerol)
Product Volume	0.25, 0.5, 1, 3, 5 and 10 cc	0.5, 1, 5 and 10 cc (Gel format)	Similar – Rafugen™ DBM is also offered in volumes of 0.25 and 3 cc.
Format types	Gel type	Various, including Gel type	Same
Osteoinductive potential	Yes, per athymic rat assay	Yes, per athymic rat assay	Same
Performance	Bone growth and remodeling in a rabbit femoral defect model	Bone growth and remodeling in a rabbit femoral defect model	Same – a comparison study was performed by Cellumed
Ready to use	Yes	Yes	Same
Presentation Type	Syringe	Syringe	Same (for Grafton® Gel)

Rafugen™ DBM is substantially equivalent to the predicate device with respect to materials in that it consists of human demineralized bone matrix (DBM) and an inert resorbable non-tissue additive or carrier. The final composition of Rafugen™ DBM was found to be biocompatible and to meet its design specifications. The addition of starch and CMC to the formulation does not raise additional or different questions of safety and effectiveness.

GRAFTON® DBM is indicated for use as a bone graft extender and for use in the posterolateral spine, whereas Cellumed is not seeking those indications for Rafugen™ DBM. The narrower indication does not raise any additional questions of safety and effectiveness.

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of Rafugen™ DBM and in showing substantial equivalence to the predicate device, Cellumed completed a number of tests. In accordance with the "Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device,"June, 2003, the following testing has been performed to support substantial equivalence:

- Chemical and physical properties
- Biocompatibility
- Sterility
- furthermore Shelf Life
- Comparison performance testing in rabbit femoral condyle model

In addition, the device was tested for osteoinductive potential using an athymic rat assay (ectopic pouch model). Osteoinduction assay results using the athymic rodent assay should not be interpreted to predict clinical performance in human subjects.

Validation was performed for the Rafugen™ DBM processing to demonstrate inactivation of a panel of model viruses.

The device was tested for material mediated pyrogenicity. The test sample of Rafugen™ DBM was extracted in endotoxin free water, and evaluated by Endosafe® PTS™ system. Under the conditions of this study, no endotoxin level showed above 0.5 EU/mL in all five batches. The test extract was judged as non-pyrogenic, and the test sample satisfied the requirements for the absence of pyrogens.

Rafugen™ DBM meets all the requirements for overall design, sterilization, biocompatibility, labeling, and performance. The testing for osteoinductive potential of both devices was demonstrated using a validated athymic rat assay, and comparison performance testing conducted in a rabbit critical size femoral defect model demonstrated equivalent bone formation and remodeling.

10. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or the device has the same intended use and different technological characteristics, but it can be demonstrated that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device as a result of the differences in technological characteristics.

It has been shown in this 510(k) submission that the minor differences between the Rafugen™ DBM and the Grafton® DBM predicate device do not raise new questions regarding its safety and effectiveness. The Rafugen™ DBM is therefore determined to be substantially equivalent to the predicate device.

12. Conclusion

The submitted 510(k) demonstrates Rafugen™ DBM is substantially equivalent to the predicate device.