Sirakoss Ltd.
% Kevin Thomas
Vice President and Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

June 9, 2020

Re: K193075
Trade/Device Name: Osteo3 ZP Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: May 8, 2020
Received: May 11, 2020

Dear Kevin Thomas:

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)*

K193075

Device Name

Osteo^3 ZP Putty

Indications for Use *(Describe)*

Osteo^3 ZP Putty is indicated for filling bone voids or defects of the skeletal system (i.e., the extremities, pelvis, and posterolateral spine) that are not intrinsic to the stability of the bony structure. These osseous defects may be surgically created or as a result of traumatic injury to the bone. Osteo^3 ZP Putty is a bone graft putty that is resorbed and replaced with bone during the healing process. Osteo^3 ZP Putty must be used with morselized autograft bone at a ratio of 1:1 by volume in the posterolateral spine.

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
K193075
Osteo^3 ZP Putty
SIRAKOSS Ltd.

May 8, 2020

ADMINISTRATIVE INFORMATION

Manufacturer Name	SIRAKOSS Ltd. Level 4, Polwarth Building, Foresterhill Aberdeen AB25 2ZD, United Kingdom Telephone +44 1224 437846
Official Contact	Jordan Conway, PhD R&D Manager
Representative/Consultant	Kevin A. Thomas, PhD Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 858-792-1235 Fax: +1 858-792-1236 Email: kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Device Name	Osteo^3 ZP Putty
Common Name	Filler, bone void, calcium compound
Regulation Number	21 CFR 888.3045
Regulation Name	Resorbable calcium salt bone void filler device
Regulatory Class	Class II
Product Code	MQV
Classification Panel	Orthopedic
Reviewing Office	Office of Health Technology 6 (Orthopedic Devices)
Reviewing Division	Division of Health Technology 6 C (Restorative, Repair and Trauma Devices)

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K140375, MASTERGRAFT® Strip; MASTERGRAFT® Putty, Medtronic Sofamor Danek USA, Inc.

Additional Predicate Device
K071206, Actifuse ™ ABX E-Z-fil Bone Graft Substitute, ApaTech Limited

Reference Device
K173525, NovoGro, OsteoNovus, Inc.

INDICATIONS FOR USE STATEMENT

Osteo[3] ZP Putty is indicated for filling bone voids or defects of the skeletal system (i.e., the extremities, pelvis, and posterolateral spine) that are not intrinsic to the stability of the bony structure. These osseous defects may be surgically created or as a result of traumatic injury to the bone. Osteo[3] ZP Putty is a bone graft putty that is resorbed and replaced with bone during the healing process. Osteo[3] ZP Putty must be used with morselized autograft bone at a ratio of 1:1 by volume in the posterolateral spine.

SUBJECT DEVICE DESCRIPTION

Osteo[3] ZP Putty is an osteoconductive, resorbable, porous, 100% nanosynthetic calcium phosphate bone void filler. Osteo[3] ZP Putty contains 5.8 wt% silicon-substituted calcium phosphate granules suspended in a resorbable polymer gel. The final, finished Osteo[3] ZP Putty is 30 wt% granules and 70 wt% polymer gel. The high surface area porous granules have been designed to deliver consistent and rapid bone ingrowth, remodeling and cell-mediated resorption during the bone healing process. The aqueous polymer gel phase binds the highly porous granules into a moldable, pliable formulation which enables Osteo[3] ZP Putty to be implanted directly from the packaging without any further gelation, mixing or graft setting time. Osteo[3] ZP Putty is provided sterile to the end user in 5 cc and 10 cc sizes.

PERFORMANCE DATA

Non-clinical testing data were submitted according to the guidance documents *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device* (issued June 2003) and *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile* (issued January 2016). The non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included chemical composition, physical properties, sterilization, material-mediated pyrogenicity, bacterial endotoxin, sterile barrier shelf life, product shelf life, and biocompatibility.

Animal testing was performed in a rabbit posterolateral spine fusion model to demonstrate substantial equivalence to the primary predicate device (K140375). Animals were evaluated after implantation with the subject device, the primary predicate device, and autograft (positive control). The study time points included baseline (time 0), 6 weeks, 9 weeks, and 12 weeks. Evaluation endpoints included manual palpation, range of motion/flexibility testing, plain and high-resolution radiography, micro-computed tomography (micro-CT) imaging, undecalcified histologic evaluation, and histomorphometric analysis. Decalcified paraffin histology sections also were graded according to ISO 10993-6 (Annex E).

A second animal study was performed in a rabbit critical-sized defect model to demonstrate substantial equivalence to the additional predicate device (K071206). Animals were evaluated after the defects were implanted with the subject device, the additional predicate device, or left unfilled (negative control). The study time points included baseline (time 0), 4 weeks, 8 weeks, and 12 weeks. Evaluation endpoints included plain and high-resolution radiography, micro-computed tomography (micro-CT) imaging, undecalcified histologic evaluation, and histomorphometric analysis. Decalcified paraffin histology sections also were graded according to ISO 10993-6 (Annex E).

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject device is substantially equivalent in indications and design principles to the primary predicate device, the additional predicate device, and the reference device listed above. Provided at the end of this summary are tables comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device, the additional predicate device, and the reference device.

The primary predicate device is K140375 for substantial equivalence in the posterolateral spine animal model performance testing. The additional predicate device K071206 is for substantial equivalence in the critical-sized defect animal model performance testing. The reference device K173525 is in support of substantial equivalence in terms of the subject device material composition.

The subject device, the primary predicate device K140375, and the additional predicate device K071206, and the reference device K173525 have the same intended use, the same product classification and product code (MQV), and have similar Indications for Use statements. The subject device, the primary predicate device, the additional predicate device, and the reference device are indicated for use as stand-alone bone void fillers in the extremities and pelvis. The subject device, the primary predicate, and the reference device K173525 are indicated for use with autograft bone (as a bone graft extender) in the posterolateral spine; the additional predicate device K071206 is indicated for stand-alone use in the posterolateral spine. Although the subject device, the primary predicate device, the additional predicate device, and the reference device have slightly different Indications for Use language, these differences in language do not change the intended use as a bone void filler.

The subject device, the primary predicate device, the additional predicate device, and the reference device all incorporate calcium phosphate materials within a polymeric binder or scaffold. The subject device polymeric binder is a resorbable polymer that is similar to that of the additional predicate device K071206. The subject device, the additional predicate device K071206, and the reference device K173525 each include silicon in the mineral component; the amount of silicon in the subject device is within the range of the amount of silicon in K071206 and K173525.

The subject device, the additional predicate device K071206, and the reference device K173525 also are similar in physical form (putty), and are provided in similar packaging to the end user (delivery syringe). The subject device, the primary predicate device, the additional predicate device, and the reference device are provided sterile for single-patient, single-use in similar ranges of graft volumes.

The radiographic, histologic, and histomorphometric performance of the subject device were compared to that of the primary predicate device K140375 in a rabbit posterolateral fusion model. The results of the study, provided in Section 19 *Performance Testing – Animal*, demonstrated that the performance of the subject device was equivalent to that of the predicate device K140375 in the posterolateral spine.

Similarly, the radiographic, histologic, and histomorphometric performance of the subject device were compared to that of the additional predicate device K071206 in a rabbit critical-sized defect model. The results of the study, also provided in Section 19, demonstrated that the performance of the subject device was equivalent to that of the predicate device K071206 in the critical-sized defects.

CONCLUSION

The subject device, the primary predicate device, the additional predicate device, and the reference device have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device, the primary predicate, the additional predicate device, and reference device encompass the same range of physical dimensions, are packaged in similar materials and are sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate device, the additional predicate device, and the reference device listed above.

Table of Substantial Equivalence

Comparison	Subject Device	Primary Predicate Device	Additional Predicate Device	Reference Device
	Osteo^3 ZP Putty SIRAKOSS Ltd.	K140375 MASTERGRAFT® Strip; MASTERGRAFT® Putty Medtronic Sofamor Danek USA, Inc.	K071206 Actifuse ™ ABX E-Z-fil Bone Graft Substitute ApaTech Limited	K173525 NovoGro OsteoNovus, Inc.
Indications for Use Statement	Osteo^3 ZP Putty is indicated for filling bone voids or defects of the skeletal system (i.e., the extremities, pelvis, and posterolateral spine) that are not intrinsic to the stability of the bony structure. These osseous defects may be surgically created or as a result of traumatic injury to the bone. Osteo^3 ZP Putty is a bone graft putty that is resorbed and replaced with bone during the healing process. Osteo^3 ZP Putty must be used with morselized autograft bone at a ratio of 1:1 by volume in the posterolateral spine.	MASTERGRAFT® Putty combined with either autogenous bone marrow, and/or sterile water, and/or autograft is indicated as a bone void filler for bony voids or gaps that are not intrinsic to the stability of the bony structure. Additionally, MASTERGRAFT® Putty can be used with autograft as a bone graft extender. MASTERGRAFT® Putty is to be gently packed into bony voids or gaps of the skeletal system (e.g., the posterolateral spine, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. MASTERGRAFT® Putty resorbs and is replaced with bone during the healing process.	Actifuse is a bone void filler intended only for orthopaedic applications as a filler for gaps and voids that are not intrinsic to the stability of the bony structure. Actifuse is indicated to be packed gently into bony voids or gaps of the skeletal system, i.e., extremities, pelvis, and spine, including use in posterolateral fusion procedures with appropriate stabilizing hardware. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.	NovoGro Putty is an implant intended to fill bony voids or gaps of the skeletal system (i.e. extremities, posterolateral spine and pelvis). NovoGro must be used with autograft as a bone extender in the posterolateral spine. These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. The device resorbs and is replaced with bone during the healing process.
Product Code	MQV	MQV	MQV	MQV
Intended Use	Bone void filler for skeletal system (extremities, pelvis, and posterolateral spine)	Bone void filler for skeletal system (extremities, pelvis, and posterolateral spine)	Bone void filler for skeletal system (extremities, pelvis, and posterolateral spine)	Bone void filler for skeletal system (extremities, pelvis, and posterolateral spine)
Reason for Predicate	*Not applicable*	Performance in animal model in the posterolateral spine (as extender with autograft)	Performance in animal model in critical-sized defects (as stand-alone bone void filler)	Reference device for silicon mineral component
Design				
Form	Irregularly shaped granules premixed with a soluble aqueous gel carrier	Granules uniformly dispersed in collagen scaffold	Irregularly shaped granules premixed with a soluble aqueous gel carrier	Regularly shaped granules premixed with a soluble polymeric binder
Granule Size	1 – 2 mm (1000 – 2000 µm)	0.5 mm – 1.6 mm in diameter	1 – 2 mm (1000 – 2000 µm)	1 – 2 mm (1000 – 2000 µm)
Porosity	Granules > 75 %	Granules – 80 % Final device – not stated in 510(k) Summary	Granules 80 %	31.3%
Materials				
Mineral component				
Calcium salts	Silicated calcium phosphate	β-tricalcium phosphate (85 %) and Hydroxyapatite (15 %)	Silicated calcium phosphate	monetite / newberyite / sodium hydrogen phosphate [$CaHPO_4$ + $Mg(PO_3OH)•3(H_2O)$ + NaH_2PO_4]
Silicon	5.8 % by weight	Not applicable	0.8 % by weight	14% by weight
Scaffold/Binder	Aqueous gel carrier (resorbable polymer)	Type I bovine collagen	Aqueous gel carrier (resorbable polymer, not specified)	Sodium carboxymethyl cellulose (CMC)
Hydrate prior to use	No	Bone marrow aspirate and/or sterile water (required)	No	Yes (supplied as dry powder and aqueous solution, mixed prior to use)
For Use in Extremities and Pelvis	Yes	Yes	Yes	Yes
Mix with bone prior to use	No	Autograft bone (optional)	No	No
For Use in Posterolateral Spine	Yes	Yes	Yes	Yes
Mix with bone prior to use	Mix with autograft bone required for posterolateral spine	Autograft bone (required)	No	Mix with autograft bone required for posterolateral spine
How Provided				
Sizes	Provided in delivery syringe Volumes: 5 cc, 10 cc	MASTERGRAFT® Putty Various volumes: 0.75 cc, 1.5 cc, 3.0 cc, 6.0 cc, and 9.0 cc packages	Provided in delivery syringe Volumes ranging from 1.5 mL to 20 mL	Provided in mixing/delivery syringe Final graft volumes ranging from 1 cc – 20 cc
Sterility	Provided sterile to end-user	Provided sterile to end-user	Provided sterile to end-user	Provided sterile to end-user
Sterilization	Gamma irradiation	Irradiation	E-beam irradiation	Gamma irradiation
Usage	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use