December 15, 2017

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

Re: K172573
Trade/Device Name: ReBOSSIS85
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: November 15, 2017
Received: November 16, 2017

Dear Dr. 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. 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,

Vincent J. Devlin -S

for

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)*

K172573

Device Name

ReBOSSIS85

Indications for Use *(Describe)*

ReBOSSIS85 is intended for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. ReBOSSIS85 is indicated to be packed gently into bony voids or gaps of the skeletal system (extremities, pelvis, and posterolateral spine). In the extremities and pelvis ReBOSSIS85 may be used without hydration or hydrated with blood. In the posterolateral spine ReBOSSIS85 is to be used hydrated with bone marrow aspirate and mixed with autograft bone. The device provides a bone void filler that is resorbed and replaced with 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
ReBOSSIS85
ORTHOREBIRTH Co., Ltd.

August 25, 2017

ADMINISTRATIVE INFORMATION

Manufacturer Name	ORTHOREBIRTH Co., Ltd. 3-17-43 Chigasaki Higashi Tsuzuki-ku Yokohama, Kanagawa, 224-0033, Japan Telephone: +81-45532-3650 Fax: +81-45532-3691
Official Contact	Yasutoshi Nishikawa, CEO
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/Proprietary Name	ReBOSSIS85
Common Name	Filler, bone void, calcium compound
Classification Name	Resorbable calcium salt bone void filler device
Classification Regulations	21 CFR 888.3045, Class II
Product Code	MQV
Classification Panel	Orthopaedic and Rehabilitation Devices Panel
Reviewing Branch	Restorative and Repair Devices Branch (RRDB)

PREDICATE DEVICE INFORMATION

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

Reference Predicate
K170620, ReBOSSIS85, ORTHOREBIRTH Co., Ltd.

INDICATIONS FOR USE

ReBOSSIS85 is intended for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. ReBOSSIS85 is indicated to be packed gently into bony voids or gaps of the skeletal system (extremities, pelvis, and posterolateral spine). In the extremities and pelvis ReBOSSIS85 may be used without hydration or hydrated with blood. In the posterolateral spine ReBOSSIS85 is to be used hydrated with bone marrow aspirate and mixed with autograft bone. The device provides a bone void filler that is resorbed and replaced with host bone during the healing process.

DEVICE DESCRIPTION

ReBOSSIS85 is a synthetic, resorbable bone void filler. It is composite material consisting of (by weight) 40% beta-tricalcium phosphate (β-TCP), 30% siloxane-containing vaterite (a form of calcium carbonate, $CaCO_3$), and 30% poly(L-lactide-co-glycolide). The electrospinning process used in manufacturing ReBOSSIS85 results in a glass wool-like physical form. Due to its physical form, ReBOSSIS85 is flexible and can easily fill defects in appropriate amounts. ReBOSSIS85 is provided sterile for single-patient, single-use.

PERFORMANCE DATA

Non-clinical testing data submitted to demonstrate substantial equivalence included chemical characterization, physical characterization, sterilization validation, shelf life validation, biocompatibility, and *in vivo* (animal) performance.

Characterization of the ReBOSSIS85 material included: true density by pycnometry, chemical composition by energy dispersive x-ray spectrometry (EDX), trace elemental analysis by inductively coupled plasma/mass spectroscopy (ICP-MS) and inductively coupled plasma/atomic emission spectroscopy (ICP-AES), residual solvents by the methods described in USP <467>, surface microstructure by scanning electron microscopy (SEM), and polymer properties by gel permeation chromatography (GPC) and differential scanning calorimetry (DSC). ReBOSSIS85 also was characterized by a variety of techniques at baseline (time zero) and after immersion in TRIS-HCl buffer media at 37 °C. The evaluations performed included: in vitro release kinetics of Si, Ca, and P ions using inductively coupled plasma spectroscopy (ICP); the pH of the solution; imaging of the material (after drying) by scanning electron microscopy (SEM); and polymer weight-average molecular weight by gel permeation chromatography (GPC).

Sterilization validation, sterile barrier shelf life, and product shelf life testing were performed using methods described in AAMI/ANSI/ISO 11137-1, AAMI/ANSI/ISO 11137-2, ASTM F1140/F1140M, and ASTM F2096.

Biocompatibility testing was performed using methods described in AAMI/ANSI/ISO 10993-1, AAMI/ANSI/ISO 10993-5, ISO 10993-10, ISO 10993-11, and ISO 10993-12. Pyrogenicity and bacterial endotoxin testing were performed using methods described in USP 39-NF 34 <151> and USP 39-NF 34 <85>.

Animal testing performed to demonstrate substantial equivalence included determination of the radiographic, histologic, and histomorphometric characteristics of the subject device and the predicate device in a rabbit posterolateral fusion model. The study time points included 4 weeks, 8 weeks, and 12 weeks. Evaluation endpoints included radiography, manual palpation, non-destructive biomechanical testing, micro-computed tomography (micro-CT) imaging, non-decalcified histologic analysis, and non-decalcified histomorphometric analysis. Histology sections also were graded according to AAMI/ANSI/ISO 10993-6 (Annex E).

EQUIVALENCE TO MARKETED DEVICE

The subject device is substantially equivalent in indications and design principles to the predicate devices listed above. A summary table comparing the Indications for Use statement and the technological characteristics of the subject device and the predicate devices is provided in the following table.

Table of Substantial Equivalence

Comparison	Subject Device	Primary Predicate Device	Reference Predicate Device
	ReBOSSIS85 ORTHOREBIRTH Co., Ltd.	K140375 MASTERGRAFT® Strip; MASTERGRAFT® Putty Medtronic Sofamor Danek USA, Inc.	K170620 ReBOSSIS85 ORTHOREBIRTH Co., Ltd.
Indications for Use Statement	ReBOSSIS85 is intended for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. ReBOSSIS85 is indicated to be packed gently into bony voids or gaps of the skeletal system (extremities, pelvis, and posterolateral spine). In the extremities and pelvis ReBOSSIS85 may be used without hydration or hydrated with blood. In the posterolateral spine ReBOSSIS85 is to be used hydrated with bone marrow aspirate and mixed with autograft bone. The device provides a bone void filler that is resorbed and replaced with host bone during the healing process..	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.	ReBOSSIS85 is intended for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. ReBOSSIS85 is indicated to be packed gently into bony voids or gaps of the skeletal system (extremities and pelvis), and may be used without hydration or hydrated with blood. The device provides a bone void filler that is resorbed and replaced with host bone during the healing process.
Product Code	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)
Design			
Form	Glass wool-like, produced by electrospinning	Granules uniformly dispersed in collagen scaffold	Glass wool-like, produced by electrospinning
Granule Size	Not applicable	0.5 mm – 1.6 mm in diameter	Not applicable
Fiber Size	nominal diameter range: 3 µm to 150 µm specification of maximum diameter: 250 µm	Not applicable	nominal diameter range: 3 µm to 150 µm specification of maximum diameter: 250 µm
Porosity	Approximately 98 % (dry, no hydration)	Granules 80%	Approximately 98 % (dry, no hydration)
Materials			
Calcium salts	β-tricalcium phosphate, 40 % by weight Siloxane-containing vaterite (SiV), 30 % by weight	β-tricalcium phosphate (85%) and Hydroxyapatite (15%)	β-tricalcium phosphate, 40 % by weight Siloxane-containing vaterite (SiV), 30 % by weight
Silicon	Approximately 0.7 % by weight Range, 0.5 % - 1 % by weight	Not applicable	Approximately 0.7 % by weight Range, 0.5 % - 1 % by weight
Scaffold/Binder	Poly(L-lactide-co-glycolide), 30% by weight	Type I bovine collagen	Poly(L-lactide-co-glycolide), 30% by weight
How Provided			
Sizes	Provided in 0.4, 0.7, 1, and 2 gram packages Approximate volume: 10-50 cc (dry, no hydration) 4-20 cc (after hydration)	Provided in 0.75 cc, 1.5 cc, 3.0 cc, 6.0 cc, and 9.0 cc packages	Provided in 0.5, 1, and 2 gram packages Approximate volume: 13-50 cc (dry, no hydration) 5-20 cc (after hydration)
Hydration prior to use	Bone marrow aspirate (required)	Bone marrow aspirate and/or sterile water (required)	Blood (optional)
Sterility	Provided sterile to end-user	Provided sterile to end-user	Provided sterile to end-user
Sterilization	Gamma irradiation	Not stated	Gamma irradiation
Usage	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use

The primary predicate device is K140375 for substantial equivalence in the animal model performance testing. The reference predicate device is K170620 in support of substantial equivalence in the physical form and the material composition.

The subject device and the primary predicate device have the same intended uses, the same product classification and product code (MQV), and have similar Indications for Use statements. The subject device and the primary predicate devices are bone void fillers that are intended for bony voids or gaps that are not intrinsic to the stability

of the bony structure. The subject device and primary predicate device are indicated for use as in the posterolateral spine with autograft bone (extender), and the subject device and primary predicate device are to be hydrated with bone marrow aspirate (primary predicate device may be hydrated with sterile water). Although the subject device and the primary predicate device have slightly different Indications for Use language, these differences do not change the intended use as a bone void filler in the posterolateral spine.

The subject device and the predicate devices all incorporate calcium phosphate materials within a polymer scaffold or binder. The subject device polymer scaffold is poly(L-lactide-co-glycolide), the predicate K140375 scaffold is type I bovine collagen. The subject device is identical to the reference predicate device K170620. The subject device and the predicate devices 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 demonstrated that the performance of the subject ReBOSSIS85 device was equivalent to that of the predicate device K140375.

No clinical data were included in this submission.

CONCLUSION

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