DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 23, 2017

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

Re: K170620
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: May 18, 2017
Received: May 19, 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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)*

K170620

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 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.

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
ORTHOREBIRTH Co., Ltd.
ReBOSSIS85

February 28, 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
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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
K071206, Actifuse™ ABX E-Z-fil Putty Bone Graft Substitute, ApaTech Limited.

Reference Predicate
K142090, REBOSSIS, 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 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.

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 radiographic, histologic and histomorphometric characteristics of the subject device and the predicate device in a rabbit distal femoral condyle critical-sized defect model. The study time points included baseline (1 day), 6 weeks, and 12 weeks. Evaluation endpoints included radiography, micro-computed tomography (micro-CT) imaging, decalcified histologic evaluation, and 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 and the technological characteristics of the subject device and the predicate devices is provided below.

Table of Substantial Equivalence

Comparison	Subject Device	Primary Predicate Device	Reference Predicate Device
	ReBOSSIS85 ORTHOREBIRTH Co., Ltd.	K071206 Actifuse™ ABX E-Z-fill Putty Bone Graft Substitute ApaTech Limited	K142090 REBOSSIS 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 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.	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.	REBOSSIS is a bone void filler 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. REBOSSIS 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 bone marrow aspirate or 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)	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	Irregularly shaped granules premixed with an aqueous gel carrier	Glass wool-like, produced by electrospinning
Granule Size	Not applicable	1 – 2 mm (1000 – 2000 µm)	Not applicable
Fiber Size	nominal fiber diameter range: 3 µm to 150 µm specification of maximum fiber diameter: 250 µm	Not applicable	nominal fiber diameter range 10 µm – 50 µm
Porosity	Approximately 98 % (dry, no hydration)	Not stated	> 98 %
Materials			
Calcium salts	β-tricalcium phosphate, 40 % by weight Siloxane-containing vaterite (SiV), 30 % by weight	Hydroxyapatite (HA)	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	0.8 % by weight	1 % by weight
Scaffold/Binder	Poly(L-lactide-co-glycolide), 30% by weight	Resorbable polymer; aqueous gel carrier	Poly(L-lactide)
How Provided			
Sizes	Provided in 0.5, 1, and 2 gram packages Approximate volume: 13-50 cc (dry, no hydration) 5-20 cc (after hydration)	Provided in delivery syringe Volumes ranging from 1.5 mL to 20 mL	Provided in 2 gram package Approximate volume: 70-80 cc
Sterility	Provided sterile to end-user	Provided sterile to end-user	Provided sterile to end-user
Sterilization	Gamma irradiation	Electron-beam irradiation	Gamma irradiation
Usage	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use

The primary predicate device is K071206 for substantial equivalence in the animal model performance testing. The reference predicate device is K142090 for support of substantial equivalence in the physical form and the material composition (same mineral components and similar resorbable polymer scaffolds).

The subject device and the predicate devices 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 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, predicate device K071206, and predicate device K142090 all have indications for use in the extremities and pelvis, and may be used without hydration or hydrated with bone marrow aspirate or blood (the subject device is to be hydrated with blood only). Although the subject device and the predicate devices have slightly different Indications for Use language, these differences do not change the intended use as a bone void filler in the extremities and pelvis.

The subject device and the predicate devices all incorporate calcium phosphate materials with Si (ReBOSSIS85 approximately 0.7% Si by weight, Actifuse ABX approximately 0.8% by weight, REBOSSIS approximately 1% Si by weight), and all also incorporate a polymeric scaffold or binder. The subject device and the reference predicate device K142090 have very similar physical forms and material components. 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 predicate device K071206 (Actifuse ABX) in a rabbit distal femoral condyle critical-sized defect model. The results of the study demonstrated that the performance of the subject ReBOSSIS85 device was equivalent to that of the predicate Actifuse ABX device.

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.