DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 29, 2014

ORTHOREBIRTH Co., Ltd.
% Kevin A. Thomas, Ph.D.
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K142090
Trade/Device Name: REBOSSIS
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: July 31, 2014
Received: August 1, 2014

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" (21CFR 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 yours,

Lori A. Wiggins -S

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

Enclosure

Indications for Use

510(k) Number: K142090

Device Name: REBOSSIS

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.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

ORTHOREBIRTH Co., Ltd.

REBOSSIS

October 28, 2014

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
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	REBOSSIS
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)

INTENDED USE

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.

DEVICE DESCRIPTION

REBOSSIS 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). The electrospinning process used in manufacturing REBOSSIS results in a glass wool-like physical form. Due to its physical form, REBOSSIS is flexible and can easily fill defects in appropriate amounts.

PERFORMANCE DATA

Pre-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included chemical composition, physical properties, biocompatibility, and performance characteristics. Biocompatibility testing was performed using methods described in ISO 10993-1, ISO 10993-3, ISO 10993-5, ISO 10993-6, ISO 10993-10, ISO 10993-11, USP 36 <85> and USP 36 <151>.

Material characterization performed 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), 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). The in vitro release kinetics of Si, Ca and P ions were measured using inductively coupled plasma spectroscopy (ICP) at multiple time points after up to 14 days in simulated body fluid. SEM, EDX, and Fourier transform infrared spectroscopy (FTIR) also were performed at time 0 and after 14 days in simulated body fluid.

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. Each material was evaluated with three (3) hydration conditions: no hydration (dry, material alone), hydrated with autologous blood, and hydrated with autologous bone marrow aspirate. Hydration with blood or bone marrow aspirate was 1:1 by volume.

The study time points included baseline (time 0), 6 weeks, and 12 weeks. The baseline (time 0) animals included REBOSSIS (dry) and Actifuse Shape (dry) to provide information on the initial amount of material implanted to fill the defects. Autograft bone filled defects (positive control) and empty unfilled defects (negative control) also were evaluated at 6 weeks and 12 weeks. Evaluation endpoints included high-resolution radiography, micro-computed tomography (micro-CT) imaging, undecalcified histologic evaluation, and histomorphometric analysis.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICE

The subject device is substantially equivalent in indications and design principles to the following predicate device:

K080736, Actifuse™ Shape, ApaTech Limited

The subject device and the predicate device are bone void fillers that are intended for bony voids or gaps that are not intrinsic to the stability of the bony structure (extremity and pelvis) and both are indicated for use without hydration or hydrated with bone marrow aspirate or blood. Any differences in the technological characteristics between the subject and predicate devices do not raise different questions of safety or effectiveness.

The data included in this submission demonstrate substantial equivalence to the predicate device listed above.

Overall, the subject device has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes.