March 4, 2024

OrthoRebirth Co., Ltd.
℅ Justin Eggleton
Vice President, Head of Musculoskeletal Regulatory Affairs
Mcra, LLC
803 7th Street NW
Washington, District of Columbia 20001

Re: K240453
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: January 17, 2024
Received: February 15, 2024

Dear Justin 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sara S. Thompson -S

For

Jesse Muir, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240453

Device Name
ReBOSSIS

Indications for Use *(Describe)*
ReBOSSIS 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. ReBOSSIS is indicated to be packed gently into bony voids or gaps of the skeletal system (extremities, pelvis, posterolateral spine, and intervertebral disc space). In the extremities and pelvis ReBOSSIS may be used without hydration or hydrated with blood. In the posterolateral spine and intervertebral disc space, ReBOSSIS is to be used hydrated with bone marrow aspirate and mixed with autograft bone. When used in intervertebral body fusion procedures, ReBOSSIS must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler. 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.

510(k) Summary

Device Trade Name: ReBOSSIS

Manufacturer:
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Office: 202.552.5800

Date Prepared: March 4, 2024

Classifications: 21 CFR §888.3045

Class: II

Product Codes: MQV

Primary Predicate: Catalyst Bone Void Filler, OssDsign AB (K232315)

Additional Predicate: ReBOSSIS85, ORTHOREBIRTH Co., Ltd. (K172573)

Indications For Use:

ReBOSSIS 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. ReBOSSIS is indicated to be packed gently into bony voids or gaps of the skeletal system (extremities, pelvis, posterolateral spine, and intervertebral disc space). In the extremities and pelvis ReBOSSIS may be used without hydration or hydrated with blood. In the posterolateral spine and intervertebral disc space, ReBOSSIS is to be used hydrated with bone marrow aspirate and mixed with autograft bone. When used in intervertebral body fusion procedures, ReBOSSIS must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler. The device provides a bone void filler that is resorbed and replaced with host bone during the healing process.

Device Description:
ReBOSSIS is composite material consisting of beta-tricalcium phosphate (β-TCP), siloxane-containing vaterite (a form of calcium carbonate, $CaCO_3$), and a resorbable scaffold of poly(L-lactide-co-glycolide), or PLGa. The electrospinning process used in manufacturing ReBOSSIS results in a glass wool-like (or cotton ball-like) physical form. Due to its physical form, ReBOSSIS is flexible and can easily adapt to and fill in defects in appropriate amounts.

Predicate Device:
ORTHOREBIRTH Co., Ltd. submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, ReBOSSIS is substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices:

Primary Predicate: Catalyst Bone Void Filler, OssDsign AB (K232315)
Additional Predicate: ReBOSSIS85, ORTHOREBIRTH Co., Ltd. (K172573)

Performance Testing Summary:
The purpose of this submission is to expand the indications for use of the ReBOSSIS device to include its use in the intervertebral disc space in conjunction with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

As the subject device is identical to the previously cleared reference device (K172573), it was determined that the non-clinical testing data and the animal testing data provided in the prior submission is adequate to support the expanded indications proposed in the current submission. A clinical rationale was provided to justify that the use of the subject device in the posterolateral spine is a worst-case use scenario and to support the performance and safety of the expanded indications for use to include use of ReBOSSIS with intervertebral body fusion devices cleared by FDA for use with bone void fillers.

In support of the prior clearance (K172573), 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 physical properties, sterilization, product shelf life, and biocompatibility.

Animal testing was performed in a rabbit posterolateral fusion model to demonstrate substantial equivalence to a legally marketed predicate device.

The performance testing and supporting clinical rationale are further detailed in the "Performance Testing" Section of the subject submission.

Substantial Equivalence:
The subject device was demonstrated to be substantially equivalent to the OssDsign Catalyst Bone Void Filler (K232315) primary predicate device with respect to indications, design principles, and performance.

The subject device and primary predicate device both perform their intended use via calcium phosphate materials and are provided in multiple volumes. The subject and primary predicate devices are provided sterile and are intended for single-patient and single-use.

The subject device is identical to the additional predicate (ReBOSSIS85, K172573). The performance of the reference device has previously been assessed at the time of prior clearance.

Non-clinical testing data and animal testing data, supplemented with a clinical rationale, are referenced to demonstrate the performance of the subject device is substantially equivalent to that of the predicate device.

Any differences in the technological characteristics between the subject and predicate devices do not raise new issues or concerns of safety or efficacy.

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 devices listed above. ReBOSSIS is as safe, as effective, and performs as well as the predicate devices.