September 15, 2023

OssDsign AB
Jonas Aberg
Regulatory Affairs Manager
Rapsgatan 23 A
Uppsala, SE 754 50
Sweden

Re: K232315
Trade/Device Name: Catalyst Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: August 2, 2023
Received: August 2, 2023

Dear Mr. Aberg:

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,

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.

Submission Number *(if known)*

K232315

Device Name

Catalyst Bone Void Filler

Indications for Use *(Describe)*

Catalyst Bone Void Filler is indicated for filling bone voids or defects of the skeletal system (i.e., the posterolateral spine, intervertebral disc space, extremities, and pelvis) 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. Catalyst Bone Void Filler is a bone graft putty that is resorbed and replaced with bone during the healing process. Catalyst Bone Void Filler must be used with morselized autograft bone at a ratio of 1:1 by volume in the posterolateral spine. When used in intervertebral body fusion procedures, Catalyst Bone Void Filler must be used with morselized autograft bone at a ratio of 1:1 by volume with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Device Trade Name:	Catalyst Bone Void Filler
Manufacturer:	OssDsign AB Rapsgatan 23 A SE 754 50 Uppsala Sweden
Contact:	Jonas Aberg Regulatory Affairs Manager OssDsign AB Rapsgatan 23A, 754 50 Uppsala Sweden Phone: +1(410) 775 5465 Email: ja@ossdsign.com
Prepared by:	MCRA, LLC 803 7th Street, NW, 3rd Floor Washington, DC 20001 Office: 202.552.5800
Date Prepared:	August 2, 2023
Classification:	21 CFR §888.3045, Resorbable calcium salt bone void filler device
Class:	II
Product Code:	MQV
Primary Predicate:	NuVasive Attrax Putty (NuVasive, Inc., K203714)
Reference Device:	Osteo^3 ZP Putty (Sirakoss Ltd., K193075)

Indications For Use:
Catalyst Bone Void Filler is indicated for filling bone voids or defects of the skeletal system (i.e., the posterolateral spine, intervertebral disc space, extremities, and pelvis) 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. Catalyst Bone Void Filler is a bone graft putty that is resorbed and replaced with bone during the healing process. Catalyst Bone Void Filler must be used with morselized autograft bone at a ratio of 1:1 by volume in the posterolateral spine. When used in intervertebral body fusion procedures, Catalyst Bone Void Filler must be

used with morselized autograft bone at a ratio of 1:1 by volume with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

Device Description:
OssDsign Catalyst is an osteoconductive, resorbable, porous, 100% nanosynthetic calcium phosphate bone void filler. OssDsign Catalyst contains 5.8 wt% silicon-substituted calcium phosphate granules suspended in a resorbable polymer gel. The final, finished OssDsign Catalyst 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 OssDsign Catalyst to be implanted directly from the packaging without any further gelation, mixing or graft setting time. OssDsign Catalyst is provided sterile to the end user in 1 cc, 2.5 cc, 5 cc, and 10 cc syringe volumes.

OssDsign Catalyst is identical to the currently marketed product Osteo^3 ZP Putty (K193075). The cleared Osteo^3 ZP Putty was launched in the USA in October 2021 and marketed under the name OssDsign Catalyst.

Predicate Device:
OssDsign AB submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, Catalyst Bone Void Filler is substantially equivalent in intended use, indications, basic design, function, and performance to the following predicate device, which has been determined by FDA to be substantially equivalent to pre-amendment devices:

Primary Predicate: NuVasive Attrax Putty, NuVasive, Inc., K203714

Reference Device:
The Catalyst Bone Void Filler subject device substantially equivalent with respect to design principles, materials, manufacturing process, and mechanical performance to the following reference device, which has been determined by FDA to be substantially equivalent to pre-amendment devices:

Reference Device: Osteo^3 ZP Putty, Sirakoss Ltd., K193075

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

Because the subject device is identical to the previously cleared reference device (K193075), it was determined that existing testing data is adequate to support the expanded indications proposed in the current submission.

In support of the prior clearance (K193075), 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, biocompatibility, and animal testing.

Substantial Equivalence:
The subject device was demonstrated to be substantially equivalent to the NuVasive Attrax Putty (K203714) primary predicate device with respect to indications, design principles, and performance.

The subject device and primary predicate device both incorporate calcium phosphate materials within a resorbable polymeric binder or scaffold, are similar in physical form (putty), and are provided in multiple size options. The subject and primary predicate devices are provided sterile using similar radiation sterilization methods and are intended for single-patient and single-use.

The reference device, Osteo^3 ZP Putty (K193075), is referenced in support of the subject device material composition, manufacturing processes, and mechanical performance testing in the posterolateral spine fusion animal model.

The subject device, the primary predicate device (K203714), and the reference device (K193075) 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, and the reference device are indicated for use as stand-alone bone void fillers in the extremities and pelvis. The subject device and reference device are indicated for use with autograft bone (as a bone graft extender) in the posterolateral spine; the primary predicate device is indicated for standalone or optional use with autograft bone in the posterolateral spine. The subject device is indicated for use in the intervertebral disc space when used with autograft bone and an intervertebral body fusion device cleared by FDA for use with a bone void filler; the primary predicate device is indicated for standalone use in the intervertebral disc space when used with an intervertebral body fusion device cleared by FDA for use with a bone void filler; the reference device is not indicated for use in the intervertebral disc space. 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. Notably, the indications for use language pertaining to the intervertebral disc space retains the identical configurations for use as those specified for the respective device's posterolateral spine indication (i.e., mixed with autograft or standalone).

The performance of the subject Catalyst Bone Void Filler has previously been assessed at the time of the prior clearance (K193075).

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 primary predicate device have the same intended use, nearly identical indications for use, are similar in physical form (putty), and have similar technological characteristics. The subject and predicate devices are provided sterile, are sterilized using similar methods, and are intended for single-patient and single-use. The data included in this submission demonstrate substantial equivalence to the predicate device and reference device listed above.