June 21, 2024

XeroThera Inc
% Mehdi Kazemzadeh-Narbat
Director, Regulatory Affairs
MCRA
803 7th Street, Floor 3
Washington, District of Columbia 20001

Re: K233259
Trade/Device Name: XeroSyn 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: May 25, 2024
Received: May 28, 2024

Dear Mehdi Kazemzadeh-Narbat:

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,

Jesse Muir -S Digitally signed by Jesse Muir -S
Date: 2024.06.21 12:12:11 -04'00'

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)*

K233259

Device Name

XeroSyn™ Bone Void Filler

Indications for Use *(Describe)*

XeroSyn bone void filler is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities and pelvis). XeroSyn is used with autograft as a bone graft extender in the extremities and pelvis. These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. XeroSyn resorbs and is replaced with 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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K233259

510(K) SUMMARY

Device Trade Name: XeroSyn Bone Void Filler

Manufacturer: XeroThera, Inc.
5 W Gay Street
West Chester, PA 19380, USA
Mobile: (908) 625-7734

Contact: Noel Rolon, MA, CT
VP Regulatory and Clinical Affairs
Mobile: (908) 625-7734
Email: rolon@xerotherainc.com

Prepared by: Mehdi Kazemzadeh-Narbat, PhD, PMP, CQA
Director, Regulatory Affairs,
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, DC 20001
Office: 202.552.6011
mkazemzadeh@mcra.com

Date Prepared: June 18, 2024

Classifications: 21 CFR §880.3045, Resorbable calcium salt bone void filler device

Class: II

Product Codes: MQV

Primary Predicate: AltaPore (K192363)

Indications For Use:
XeroSyn bone void filler is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities and pelvis). XeroSyn is used with autograft as a bone graft extender in the extremities and pelvis. These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. XeroSyn resorbs and is replaced with bone during the healing process.

Device Description:
XeroSyn bone void filler is a synthetic bone graft substitute designed for use as an autograft extender in the extremities and the pelvis. XeroSyn bone void filler is a sol-gel synthesized

bioactive, osteoconductive bone void filler. The chemical composition of XeroSyn is very similar to the predicate, Altapore, containing elements that exist naturally in bone (Ca, P, O, H, Si), albeit at different ratios. The sol-gel synthesis process produces porous microparticles which are silane treated to enhance the particle growth to form the desired granule size. The interconnected highly porous structure of XeroSyn readily absorbs body fluids and facilitates quick and easy mixing with autogenous bone.

XeroSyn bone void filler is supplied in a sterile glass vial within a sterile pouch and contains 1 gram of XeroSyn micro-granules sized 20-30 µm, 80% total porosity, and appears as a fine white powder. XeroSyn does not set *in situ* following implantation.

XeroSyn is bioactive as supported by the Kokubo test. This *in vitro* test shows the formation of a surface apatite layer when the synthetic graft material is immersed in a standard simulated body fluid with the ion concentration of human blood plasma. This apatite layer provides scaffolding onto which the patient's new bone will grow.

Predicate Device:

XeroThera Inc. submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, XeroSyn is substantially equivalent in intended use, indications, design principles, and performance to the following predicate device, which has been determined by FDA to be substantially equivalent to pre-amendment devices:

Predicate: AltaPore (K192363)

Performance Testing Summary:

Bench testing including analytical characterization, chemical composition, physical properties, and animal functional studies were conducted for the subject XeroSyn and predicate device. The results of the studies demonstrate substantial equivalence to the predicate device.

Substantial Equivalence:

Each of the following test results met the acceptance criteria and support the substantial equivalence of the proposed device as compared to the predicate for its intended use.

Bench Testing

XeroSyn is bioactive based on *in vitro* studies with the Kokubo test that show it forms a surface apatite layer when submerged in simulated body fluid that contains the same ion concentrations as human blood plasma. The SEM and FTIR spectral analyses reveal the formation of crystalline carbonated apatite (c-AP) on the surface of XeroSyn after 2 days of immersion. This apatite layer provides scaffolding onto which the patient's new bone will grow. Similarly, the predicate device forms an apatite layer on its surface after immersion in simulated body fluids. These results demonstrate similar bioactivity for XeroSyn when compared to the predicate device.

Bench testing including chemical composition, and physical properties, were conducted for the subject XeroSyn device. The results of the studies demonstrate substantial equivalence to the predicate device.

Biocompatibility Testing

XeroSyn has been assessed in accordance with the requirements of ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process". The full complement of testing included the following battery of tests which all confirmed the biocompatibility of the device:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Subacute/Subchronic Toxicity
- Material-Mediated Pyrogenicity
- Genotoxicity

Animal Testing

The *in vivo* response to XeroSyn and the AltaPore predicate device were evaluated and compared at 2, 4, 6 and 12 weeks after implantation using a standard and reproducible critical size cancellous bone defect model in skeletally mature female New Zealand (NZ) White Rabbits. The results of this study were used to determine safety and effectiveness for use in extremities when mixed with autogenous iliac crest bone graft.

The subject device and the predicate device have the same intended uses, the same product classification and product code (MQV) and have similar "Indications for Use" statements in the extremities and pelvis. The subject device and the predicate devices are bone void fillers and bone graft extenders that are intended for bony voids or gaps that are not intrinsic to the stability of the bony structure. The subject device and the primary predicate incorporate the same basic design, similar materials, and are both provided sterile for single-patient and single-use.

No clinical data were required to support the substantial equivalence.

Table 1. Substantial Equivalence of the Subject and Predicate Device.

Attribute	**XeroSyn (Subject Device)**	**AltaPore (K192363)**
Intended Use	XeroSyn bone void filler is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities and pelvis).	AltaPore is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities, posterolateral spine and pelvis).
Indications for Use Statement	XeroSyn bone void filler is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities and pelvis). XeroSyn is used with autograft as a bone graft extender in the extremities and pelvis. These osseous defects may be surgically created or the	AltaPore is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities, posterolateral spine and pelvis). AltaPore can be used by itself, with autograft as a bone graft extender or with autogenous bone marrow aspirate. These osseous defects may

	result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. XeroSyn resorbs and is replaced with bone during the healing process.	be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. AltaPore resorbs and is replaced with bone during the healing process.
Chemical Composition	Silicon dioxide glass containing calcium oxide and phosphorous pentoxide composed solely of elements that exist naturally in normal bone (Ca, P, O, H, Si).	Calcium Phosphate Salt: Silicate-substituted calcium phosphate composed solely of elements that exist naturally in normal bone (Ca, P, O, H, Si).
Design	microgranules, sized 20-30 µm in fine powder form	microgranules, sized 1-2 mm
Porosity	80 ± 2%	82.5 ± 2.5%
Osteoconductivity	Osteoconductive	Osteoconductive
Bioactivity	Bioactive, forms surface apatite layer after implantation	Bioactive, forms surface apatite layer after implantation
Resorption	Device degrades and resorbs over time	Device degrades and resorbs over time
Biocompatibility	Established, ISO 10993	Established, ISO 10993
Sterility	SAL of 10^{-6}, Dry Heat	SAL of 10^{-6}, Irradiation
Packaging	Sterile, single use	Sterile, single use
Duration of Implant	About 6 weeks	More than 12 weeks

Conclusion:
The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above. XeroSyn bone void filler is as safe, as effective, and performs as well as, or better, than the predicate device.