September 13, 2018

Xenco Medical, LLC
Gustavo R. Prado, Ph.D.
Vice President, R&D
9930 Mesa Rim Road
San Diego, California 92121

Re: K173933
Trade/Device Name: Sorrento™ Bioglass Bone Graft Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: August 14, 2018
Received: August 15, 2018

Dear Dr. Prado:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurence D. Coyne -S

For 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173933

Device Name
Sorrento™ Bioglass Bone Graft Substitute

Indications for Use *(Describe)*
Sorrento Bone Graft Substitutes are intended for use as a bone void filler to fill voids or gaps of the skeletal system in the extremities and pelvis not intrinsic to the stability of the bony structure. Sorrento Bone Graft Substitutes are also indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone. Sorrento Bone Graft Substitutes must be wetted with bone marrow aspirate. Following placement in the bony void or gap (defect), Sorrento Bone Graft Substitutes are resorbed and 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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510(k) SUMMARY

I. SUBMITTER

Xenco Medical, LLC.

Contact Person: Gustavo Prado PhD
Email: gprado@xencomedical.com

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Phone: 858-202-1505 ext 202
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Date Prepared: 08/14/2018
Establishment Registration: 3011181154

II. DEVICE

SUBJECT DEVICE

Trade Name: Sorrento™ Bioglass Bone Graft Substitute
Common Name: bone void filler
Classification Name: Resorbable Calcium Salt Bone Void Filler Device
Regulation: 21 CFR 888.3045
Device Class: Class II
Product Code: MQV
Review Panel: Orthopedic

PREDICATE DEVICE

510(k) Number	Product Code	Trade Name	Manufacturer
K141429 Primary	MQV	Sorrento™ Bone Graft Substitute	Xenco Medical, LLC.
K083033 Reference	MQV	Vitoss® Foam Bone Graft Material, Vitoss® Bioactive Foam Bone Graft Substitute	Orthovita, Inc.

III. DEVICE DESCRIPTION

Sorrento BioGlass Bone Graft Substitute is a resorbable bone void filler made from a matrix of highly purified collagen (ASTM F2212) that has high porosity beta tricalcium phosphate (TCP) granules (ASTM F1088) and Bioglass 45S5 (ASTM F1538) dispersed throughout. The implant is provided as sterile, for single-use in double peel packages.

IV. INDICATIONS FOR USE

Sorrento Bone Graft Substitutes are intended for use as a bone void filler to fill voids or gaps of the skeletal system in the extremities and pelvis not intrinsic to the stability of the bony structure. Sorrento Bone Graft Substitutes are also indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone. Sorrento Bone Graft Substitutes must be wetted with bone marrow aspirate. Following placement in the bony void or gap (defect), Sorrento Bone Graft Substitutes are resorbed and replaced with bone during the healing process

V. TECHNOLOGICAL CHARACTERISTICS

The subject device is substantially equivalent to the cited legally marketed predicate Sorrento (K141429) device. The subject device has equivalent technological characteristics including design, materials, operating principle and indications for use, physical structure, product sizing, chemical composition, mineral phase, porosity, and resorption.

Chart comparing subject device to the predicate devices:

Characteristic	**Sorrento BioGlass (Subject Device)**	**Sorrento (Predicate, K141429)**	**Vitoss Foam Bone Graft Substitute and Vitoss Bioactive Foam Bone Graft Substitute (Reference, K083033)**
Materials	• Beta Tricalcium Phosphate per ASTM F1088 • Type I bovine collagen per ASTM F2212 • Bioglass 45S5 per ASTM F1538	• Beta Tricalcium Phosphate per ASTM F1088 • Type I bovine collagen per ASTM F2212	• Beta Tricalcium Phosphate per ASTM F1088 • Type I bovine collagen per ASTM F2212 • Bioglass (Bioactive version only)
Physical Structure (Form)	• Porous collagen sponge (strip) with beta-TCP/Bioglass granules • Trabecular structure similar to cancellous bone	• Porous collagen sponge (strip) with beta-TCP granules • Trabecular structure similar to cancellous	• Porous collagen sponge (strip) with beta-TCP granules • Trabecular structure similar to cancellous bone

		bone	
Dosage Forms (Sizing)	• 2cc (25 x 20 x 4 mm) • 5 cc (25 x 50 x 4 mm) • 10 cc (100 x 20 x 5 mm) • 12 cc (100 x 20 x 6 mm) • 20 cc (100 x 25 x 8 mm) • 24 cc (25 x 240 x 4 mm)	• 5 cc (25 x 50 x 4 mm) • 10 cc (100 x 20 x 5 mm) • 12 cc (100 x 20 x 6 mm) • 20 cc (100 x 25 x 8 mm) • 24 cc (25 x 240 x 4 mm)	• 2 cc (25 x 20 x 4mm) • 5 cc (25 x 50 x 4mm) (Bioactive) • 10 cc (100 x 25 x 4 mm) (Bioactive) • 10 cc (25 x 50 x 8) • 20 cc (100 x 25 x 8 mm) (Bioactive) • 24 cc (25 x 240 x 4 mm) • 30 cc (75 x 100 x 4 mm)
Chemical Composition (Chemistry)	• Calcium salt with Type **I** bovine collagen and Bioglass (~90:5:5 w/w)	• Calcium salt with Type **I** bovine collagen (~95:5 w/w)	• Calcium salt with Type **I** bovine collagen (~80:20 w/w), • Calcium salt with Type I bovine collagen and Bioglass
Mineral Phase	• Beta-Tricalcium Phosphate $Ca_3(PO4)_2$	• Beta-Tricalcium Phosphate $Ca_3(PO4)_2$	• Beta-Tricalcium Phosphate $Ca_3(PO4)_2$
Porosity (beta-TCP)	• Highly porous, >80% • Bioglass 64-78%	• Highly porous, >80%	• Approximately 90% (non-Bioactive)
Pore Size (range) (Beta-TCP)	~1-732 µm (312 ± 140 µm) bioglass	• ~1-732 µm (312 ± 140 µm)	• ~12-700 µm (non-Bioactive)
Resorption (Dissolution/ Solubility)	• Resorbable	• Resorbable	• Demonstrated 80% resorbed at 12 weeks

VI. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

Analysis was performed according to ISO 10993-1:2009 and biological effects were considered based on FDA Guidance, "Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process." Material-Mediated Pyrogenicity, Cytotoxicity, Irritation, Sensitization, and Implantation testing was performed and showed acceptable biological safety profiles. Bacterial endotoxin testing was performed and confirmed an endotoxin level within the established acceptance criteria.

Bench Testing

Substantial equivalence of the Sorrento BioGlass Bone Graft Substitute was supported by evaluation per ASTM F1088 (for beta tricalcium phosphate), ASTM F2212 (for collagen) and ASTM F1538 (Bioglass).

Bioactivity was also evaluated through analysis by SEM and FTIR to confirm the ability of the subject device to form an in vitro layer of apatite.

Animal Study

A distal femoral defect model in rabbits was used to compare the subject device to the predicate device Sorrento Bone Graft Substitute (K141429) and the reference device Vitoss Foam Bone Graft Substitute (K083033) at 3, 6 and 12 weeks following implantation. Performance was evaluated radiographically and histomorphometrically. Study data demonstrated that the subject device is substantially equivalent with the predicate and reference devices. In addition, substantial equivalence of the Sorrento BioGlass Bone Graft Substitute was supported by evaluation per ASTM F1088 (for beta tricalcium phosphate) and ASTM F2212 (for collagen) and ASTM F1538 (Bioglass).

Clinical Studies

Clinical performance data was not required to determine substantial equivalence

VII. CONCLUSIONS

Conclusions drawn from the non-clinical tests demonstrated that the subject device possessed at least equivalent performance characteristics as the predicate device, and that overall the subject device is substantially equivalent.