September 27, 2019

Xenco Medical, LLC
℅ Gustavo R. Prado, Ph.D.
President
Converg Engineering, LLC
2305 Historic Decatur Road, Suite 100
San Diego, California 92106

Re: K191074
Trade/Device Name: Sorrento™ 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 21, 2019
Received: August 30, 2019

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/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,

Laurence D. Coyne, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191074

Device Name
Sorrento™ Bone Graft Substitute

Indications for Use *(Describe)*
Sorrento Bone Graft Substitute is intended for use as a bone void filler to fill voids or gaps of the skeletal system not intrinsic to the stability of the bony structure (extremities, pelvis, posterior lateral spine). Sorrento Bone Graft Substitute is 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 Substitute must be wetted with bone marrow aspirate or, when used in the posterolateral spine, autologous bone must also be added (50/50 ratio by volume). 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: Jason Haider
Email: jhaider@xencomedical.com

9930 Mesa Rim Road
San Diego, CA 92121 USA
Phone: 858-202-1505 ext 202
Fax: 858-202-1549
Date Prepared: 12/15/2018
Establishment Registration: 3011181154

II. APPLICATION CORRESPONDENT

Converg Engineering, LLC
Contact Person: Gustavo R. Prado, Ph.D.
Email: gprado@convergeng.com

III. DEVICE

SUBJECT DEVICE

Trade Name: Sorrento™ 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.

K082166	MQV	Mastergraft Strip	Medtronic, Inc.

IV. DEVICE DESCRIPTION

Sorrento 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) dispersed throughout. The implant is provided as sterile, for single-use in double peel packages.

V. INDICATIONS FOR USE

This submission expands the indications for use of Sorrento Bone Graft Substitute for fusion in the posterior lateral spine when used with autograft bone:

Sorrento Bone Graft Substitute is intended for use as a bone void filler to fill voids or gaps of the skeletal system not intrinsic to the stability of the bony structure (extremities, pelvis, posterior lateral spine). Sorrento Bone Graft Substitute is 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 Substitute must be wetted with bone marrow aspirate or, when used in the posterolateral spine, autologous bone must also be added (50/50 ratio by volume). Following placement in the bony void or gap (defect), Sorrento Bone Graft Substitutes are resorbed and replaced with bone during the healing process

VI. 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 (Subject Device)**	**Sorrento (Predicate, K141429)**	**Mastergraft Strip (Predicate, K082166)**
Materials	• 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	• Beta Tricalcium Phosphate per ASTM F1088 • Hydroxyapatite per ASTM F1185 • Type I bovine collagen

Physical Structure (Form)	• Porous collagen sponge (strip) with beta-TCP granules • Trabecular structure similar to cancellous bone	• Porous collagen sponge (strip) with beta-TCP granules • Trabecular structure similar to cancellous bone	• Porous collagen sponge (strip) with beta-TCP and Hydroxyapatite granules • Trabecular structure similar to cancellous 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) • 10 cc (100 x 25 x 4 mm) • 10 cc (25 x 50 x 8) • 20 cc (100 x 25 x 8 mm) • 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 (~95:5 w/w)	• Calcium salt with Type **I** bovine collagen (~95:5 w/w)	• Calcium salt with Type **I** bovine collagen (~80:20 w/w),
Mineral Phase	• Beta-Tricalcium Phosphate $Ca_3(PO4)_2$	• Beta-Tricalcium Phosphate $Ca_3(PO4)_2$	• Beta-Tricalcium Phosphate $Ca_3(PO4)_2$

VII. PERFORMANCE DATA

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

Biocompatibility Testing

Biocompatibility performance data was not required to determine substantial equivalence. No changes to the product was made from the original submission.

Bench Testing

Biocompatibility performance data was not required to determine substantial equivalence. No changes to the product was made from the original submission.

Animal Study

A comprehensive Posterior Lateral Fusion (PLF) animal study was conducted and has demonstrated substantial equivalence to the Predicate Device Mastergraft Strip (K082166) with regards to the expansion of the indications for use.

Clinical Studies

Clinical performance data was not required to determine substantial equivalence

VIII. 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.