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

August 24, 2018

Re: K180373
Trade/Device Name: CancelleX Porous Titanium Lumbar Interbody Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: July 25, 2018
Received: July 27, 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,

Melissa Hall -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)*

K180373

Device Name

CancelleX Porous Titanium Lumbar Interbody Device

Indications for Use *(Describe)*

CancelleX Porous Titanium Lumbar Interbody System devices are intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non- fusion spinal surgery at the involved spinal level(s). The device is intended to be used with supplemental fixation systems that have been cleared for use in the lumbrosacral spine (e.g. posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation. The device is intended to be used with autogenous bone graft. Patients must have undergone a regimen of at least six months of non-operative treatment prior to being treated with the CancelleX device.

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.

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510(k) SUMMARY

I. SUBMITTER

Xenco Medical, LLC.

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San Diego, CA 92121 USA
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Date Prepared: 07/25/2018

Establishment Registration: 3011181154

II. DEVICE

SUBJECT DEVICE

Trade Name: CancelleX Porous Titanium Lumbar Interbody Device
Common Name: intervertebral fusion device with bone graft, lumbar
Classification Name: Intervertebral body fusion device
Regulation: 21 CFR 888.3080
Device Class: Class II
Product Code: MAX
Review Panel: Orthopedic

PREDICATE DEVICES

Type	510(k) #	Trade Name	Manufacturer	Product Code
Primary Predicate	K143158	Xenco Medical Lumbar Interbody System	Xenco Medical, LLC.	MAX
Additional Predicates				
Predicate	K150481	Cascadia Interbody System	K2M	MAX
Predicate	K152011	Lucent XP Ti-Bond®	Spinal Elements, Inc.	MAX
Reference Predicates				
Reference	K081171	Tritanium® Acetabular Shell System	Howmedica	LPH

III. DEVICE DESCRIPTION

CancelleX Porous Titanium Lumbar Interbody devices are being added to the Lumbar Interbody System. The CancelleX Porous Titanium Interbody devices are generally box shaped with surface teeth and a central channel for packing autogenous bone. These implants are available in a range of shapes and sizes to accommodate variations in patient anatomy. The devices are manufactured from Commercially Pure Titanium (ASTM F67). The system also includes instruments manufactured using polyacrylamide (PARA-IXEF-GY51) polymer and stainless steel per ASTM F899.

IV. INDICATIONS FOR USE

CancelleX Porous Titanium Lumbar Interbody devices are intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non- fusion spinal surgery at the involved spinal level(s). The device is intended to be used with supplemental fixation systems that have been cleared for use in the lumbrosacral spine (e.g. posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). Hyperlordotic interbody devices (≥20˚ lordosis) must be used with at least anterior supplemental fixation. The device is intended to be used with autogenous bone graft. Patients must have undergone a regimen of at least six months of non-operative treatment prior to being treated with the CancelleX device.

V. TECHNOLOGICAL CHARACTERISTICS

The subject device is substantially equivalent to the cited legally marketed predicate devices. The subject device has equivalent technological characteristics including design, materials, operating principle and indications for use.

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."

Bench Testing

Substantial equivalence of the CancelleX Porous Titanium Interbody Device was supported by evaluation per ASTM F2077 (Test Methods for Intervertebral Body Fusion Devices), ASTM F2267 (Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression), Expulsion testing

Animal Study

Animal performance data was not required to determine substantial equivalence.

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.