January 29, 2025

Xenco Medical, LLC
% Jeffrey Brittan
Vice President of Product Realization
Watershed Idea Foundry, Inc. (dba SpiTrex 3D)
1815 Aston Ave., Ste 106
Carlsbad, California 92008

Re: K243673
Trade/Device Name: Xenco Medical CancelleX Cervical Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: November 19, 2024
Received: November 27, 2024

Dear Jeffrey Brittan:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Brent Showalter -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243673

Device Name

Xenco Medical CancelleX Cervical Interbody System

Indications for Use *(Describe)*

Xenco Medical CancelleX Cervical Interbody System devices are intended for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Devices are to be implanted via an open, anterior approach and packed with autogenous bone. Patients should have had at least six weeks of non-operative treatment prior to surgical treatment with the device. The device is intended to be used with supplemental fixation (e.g. anterior plate system).

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:
Xenco Medical CancelleX Cervical Interbody System

Date Prepared	November 7, 2024
Applicant	Xenco Medical, LLC Jason Haider, Founder and CEO 9930 Mesa Rim Rd San Diego, CA 92121 858-202-1522 ext. 202 jhaider@xencomedical.com
Correspondent / Consultant	Jeffrey Brittan Vice President of Product Realization Watershed Idea Foundry, Inc. (dba SpiTrex 3D) jeffbrittan@spitrexorthopedics.com
Trade Name	Xenco Medical CancelleX Cervical Interbody System
Common Name	Intervertebral body fusion device
Code – Classification	Classification Name: Intervertebral Fusion Device With Bone Graft, Cervical Regulation Number: 21 CFR 888.3080 Product Code: ODP
Primary Predicate Device	K140786 Xenco Medical Cervical Interbody System Product Code: ODP
Additional Predicate Device	K222015 Integral Titanium Cervical Interbody Product Code: ODP
Device Description	Xenco Medical CancelleX Cervical Interbody System 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. Spacers are manufactured from Titanium Alloy (TI-6AL-4V per ASTM F3001-14). The system also includes instruments manufactured using 6061 T6 Aluminum Alloy (per ASTM B211 / B221) and Stainless Steel (per ASTM F899). All system implants and instruments are provided sterile packaged and are intended for single use.
Indications for Use Statement	Xenco Medical CancelleX Cervical Interbody System devices are intended for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Devices are to be implanted via an open, anterior approach and packed with autogenous bone. Patients should have had at least six weeks of non-operative treatment prior to surgical treatment with the device. The device is intended to be used with supplemental fixation (e.g. anterior plate system).
Indication for Use Comparison	The subject device has the same intended use/indications for use as the primary predicate.

Technological Comparison	The subject device has equivalent technological characteristics and performance as the predicates. The subject device is designed in the same sizes and geometries with equivalent features as the primary predicate but is 3D printed from titanium, which allows inclusion of porous latticed areas. These porous features are equivalent to the additional predicate, which is also 3D printed using titanium and equivalently incorporates lattice. The subject device and the predicates all utilize equivalent design and sizing for equivalent functionality. These devices are all generally box shaped with hollow channels to accommodate packing with bone graft, as well as anterior holes for mating with an insertion instrument. The subject devices and predicates also equivalently incorporate linear rows of anti-migration features on the superior and inferior surfaces.
Non-Clinical Test Summary & Conclusions	Bench top mechanical testing was performed, which addresses recommendations from the FDA Class II Special Controls Guidance Document - Intervertebral Body Fusion Device: • Static and dynamic axial compression, compression shear, and torsion per ASTM F2077 • Subsidence per ASTM F2267 • Expulsion testing per lab protocol Clinical testing was not applicable for this submission. The non-clinical testing demonstrates that the subject device has at least equivalent mechanical strength as the predicates. Based on the similarities of the intended use/indications for use, technological and functional characteristic, and the results of the non-clinical performance testing, the subject device is substantially equivalent to and would perform as well as the legally marketed predicate devices.