June 7, 2023

Xenco Medical, LLC
% Linda Braddon, Ph.D.
CEO
Secure BioMed Evaluations
7828 Hickory Flat Highway Suite 120
Woodstock, Georgia 30188

Re: K223059
Trade/Device Name: Xenco Medical InterAlign Cervical Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: May 10, 2023
Received: May 12, 2023

Dear Dr. Braddon:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223059

Device Name
Xenco Medical InterAlign Cervical Interbody System

Indications for Use *(Describe)*
When used as an intervertebral fusion device with bone graft, cervical:

Xenco Medical InterAlign 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).

When used as an intervertebral fusion device w/ integrated fixation, cervical (interbody spacer w/ provided plate, bone screws, and locking cover):

Xenco Medical InterAlign Cervical Interbody System constructs are stand-alone anterior cervical interbody fusion devices intended for use as an adjunct to fusion at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as discogenic neck pain with degeneration of the disc confirmed by history and radiographic studies). Patients should have received at least six weeks of non-operative treatment prior to treatment with the device. Xenco Medical InterAlign Cervical Interbody System constructs are to be packed with autogenous bone graft and implanted via an open, anterior approach. Xenco Medical InterAlign Cervical Interbody System constructs are intended to be used with the plate, bone screws, and locking cover provided and require no additional fixation.

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:
Xenco Medical IntelAlign Cervical Interbody System

Date Prepared	May 31, 2023
Sponsor	Xenco Medical, LLC Jason Haider, Founder and CEO 9930 Mesa Rim Rd San Diego, CA 92121 858-202-1522 ext. 202 jhaider@xencomedical.com
510(k) Contact(s)	Secure BioMed Evaluations Linda Braddon, Ph.D. Justin Gracyalny, MSE 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 770-837-2681 Regulatory@SecureBME.com
Trade Name	Xenco Medical IntelAlign Cervical Interbody System
Code – Classification	Classification Name: Intervertebral body fusion device (21 CFR 888.3080) Regulatory Class: Class II Product Code: OVE, ODP
Primary Predicate Device	K160313 Xenco Medical Cervical Interbody System
Additional Predicate Device	K140786 Xenco Medical Cervical Interbody System
Reference Device	K112913 DePuy Spine, Inc. Spotlight Access System
Device Description	Xenco Medical IntelAlign 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 PEEK polymer (Zeniva ZA-500 per ASTM F2026) and contain titanium (per ASTM F67), titanium alloy (per ASTM F1472), or tantalum (per ASTM F560) markers to assist with radiographic visualization. Stand-alone device constructs additionally utilize a fixation plate and bone screws manufactured from titanium alloy, and a PEEK locking cover. The system also includes instruments manufactured using anodized 6061 T6 aluminum alloy per ASTM B211 / B221. All system implants and instruments are provided sterile packaged and are intended for single use.

Indications for Use Statement	<u>When used as an intervertebral fusion device with bone graft, cervical:</u> Xenco Medical IntelAlign 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). <u>When used as an intervertebral fusion device w/ integrated fixation, cervical (interbody spacer w/ provided plate, bone screws, and locking cover):</u> Xenco Medical IntelAlign Cervical Interbody System constructs are stand-alone anterior cervical interbody fusion devices intended for use as an adjunct to fusion at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as discogenic neck pain with degeneration of the disc confirmed by history and radiographic studies). Patients should have received at least six weeks of non-operative treatment prior to treatment with the device. Xenco Medical IntelAlign Interbody System constructs are to be packed with autogenous bone graft and implanted via an open, anterior approach. Xenco Medical IntelAlign Cervical Interbody System constructs are intended to be used with the plate, bone screws, and locking cover provided and require no additional fixation.
Technological Characteristics	There are no significant technological differences between the subject and predicate device. The subject device implants are identical to those of the primary predicate (K160313). The only difference between the subject and predicate device is the material of manufacture for the instrumentation which is identical to the reference device (K112913). As supported by the non-clinical performance testing, this difference does not raise new concerns for safety or effectiveness.
Performance Testing	As the implants are identical to those cleared in K160313 and no changes have been made to indications or claims, no new non-clinical performance testing was required for the subject device implants. The subject device instrumentation is manufactured identically to those described in the reference device (K112913). As such, no biocompatibility testing was required to support the change. A gamma sterilization validation was performed to support the change in device material.
Conclusion	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 the legally marketed predicate device.