Xenco Medical, LLC
% Linda Braddon, PhD
President / CEO
Secure BioMed Evaluations
7828 Hickory Flat Hwy, Suite 120
Woodstock, Georgia 30188

December 21, 2021

Re: K213456
Trade/Device Name: Xenco Medical Multilevel CerviKit
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: October 25, 2021
Received: October 26, 2021

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,

for

Colin O'Neill, M.B.E.
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)*

K213456

Device Name
Xenco Medical Multilevel CerviKit

Indications for Use *(Describe)*

The Xenco Medical Multilevel CerviKit is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to T1). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) spondylolisthesis, 3) trauma (including fractures or dislocations), 4) tumors, 5) deformity (defined as kyphosis, lordosis, or scoliosis), 6) pseudarthrosis, 7) failed previous fusions and/or 8) spinal stenosis.

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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*5*10(k) Summary: Xenco Medical Multilevel CerviKit

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	December 20, 2021
Submitted By	Xenco Medical, LLC 9930 Mesa Rim Rd San Diego, CA 92121 858-202-1505 email: sales@xencomedical.com
Contact	Secure BioMed Evaluations 7828 Hickory Flat Hwy, Suite 120 Woodstock, GA 30188 770-837-2681 Contact: Linda Braddon e-mail: Regulatory@SecureBME.com
Trade Name	Xenco Medical Multilevel CerviKit
Common Name	Anterior Cervical Plate
Classification Name	Spinal intervertebral body fixation orthosis
Class	II
Product Code	KWQ
CFR Section	21 CFR section 888.3060
Device Panel	Orthopedic
Primary Predicate Device	K160702 Astura Medical ZION Anterior Cervical Fixation System
Additional Predicate Device	K080646 Biomet C-TekV MaxAnrm Anterior Cervical Plate
Reference Devices	K160313 Xenco Medical Cervical Interbody System K191074 Xenco Medical Sorrento Bone Graft Substitute
Device Description	The Xenco Medical Multilevel CerviKit is intended for anterior screw fixation of the plate to the cervical spine. The fixation construct consists of a cervical plate that is attached to the vertebral body of the cervical spine with bone screws using an anterior approach. Plates are available in a variety of lengths addressing multiple levels of fixation. The Xenco Medical Multilevel CerviKit plate incorporates graft windows on the longitudinal center line for intraoperative visualization and for screw fixation of bone graft. Fixed or variable bone screws are available in two diameters and a variety of lengths.

Materials	Titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136
Substantial Equivalence Claimed to Predicate Devices	The Xenco Medical Multilevel CerviKit is substantially equivalent to the predicate devices in terms of intended use, design, materials used, and mechanical performance.
Indications for Use	The Xenco Medical Multilevel CerviKit is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to T1). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) spondylolisthesis, 3) trauma (including fractures or dislocations), 4) tumors, 5) deformity (defined as kyphosis, lordosis, or scoliosis), 6) pseudarthrosis, 7) failed previous fusions and/or 8) spinal stenosis.
Non-clinical Test Summary	The following analyses were conducted: • Static and dynamic compression testing per ASTM F1717 • Static torsion testing per ASTM F1717 • Push-out testing for screws The results of these evaluations indicate that the Xenco Medical Multilevel CerviKit is equivalent to the predicate devices.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-clinical and Clinical	Xenco Medical considers the Multilevel CerviKit to be substantially equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials, and indications for use.