Met One Technologies
Mr. Evan Carbonell
President & CEO
513 W. San Antonio Ave, Suite C
El Paso, Texas 79901

May 12, 2020

Re: K193457
Trade/Device Name: AUDERE Lumbar Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: January 24, 2020
Received: February 13, 2020

Dear Mr. Carbonell:

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
Brent Showalter, Ph.D.
Assistant Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193457

Device Name
AUDERE Lumbar Spacer System

Indications for Use *(Describe)*

The AUDERE Lumbar Spacer System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S1) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at the involved level may be treated with the AUDERE Lumbar Spacer System.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the AUDERE Lumbar Spacer System.

The AUDERE Lumbar Spacer System is designed for use with autogenous bone graft. The system is also intended to be used with supplemental fixation systems that are cleared by the FDA for use in the lumbar spine.

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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K193457 - 510(K) Summary

Date:	20 April 2020
Sponsor:	Met One Technologies, LLC 513 W. San Antonio Ave Ste. C El Paso, TX 79901
Sponsor Contact	Kyle Atwood, Vice President, Engineering
Proposed Trade Name:	AUDERE Lumbar Spacer System
Common Name:	Interbody Fusion System
Device Classification:	Class II
Regulation Name, Regulation Number, Product Code:	Intervertebral fusion device with bone graft, lumbar, 888.3080, MAX
Submission Purpose:	The purpose of this submission is to address dimensional changes of the AUDERE Lumbar Spacer System for the purpose of improving insertion, better radio-visibility and to expand the system to include 4° and 8° lordotic implantable devices.
Device Description:	The AUDERE Lumbar Spacer System consists of implants and trials that are compatible with all previously cleared AUDERE instruments. The AUDERE Lumbar Spacer System may be implanted bilaterally using a posterior (PLIF) approach, or as a single device employing a transforaminal (TLIF) approach.
Indications for Use:	The AUDERE Lumbar Spacer System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S1) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at the involved level may be treated with the AUDERE Lumbar Spacer System. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the AUDERE Lumbar Spacer System. The AUDERE Lumbar Spacer System is designed for use with autogenous bone graft. The system is also intended to be used with supplemental fixation systems that are cleared by the FDA for use in the lumbar spine.
Materials:	The AUDERE Lumbar Spacer System is comprised of a family of implants that has bodies manufactured from polyetheretherketone (PEEK), in compliance with ASTM F2026, and radiographic markers manufactured from Tantalum, in compliance with ASTM F560.

Primary Predicate	AUDERE Lumbar Spacer System (Met One Technologies, LLC – K160699)
Additional Predicates	PATRIOT™ Spacer (Globus Medical Inc. – K122097) Interbody System (Tyber Medical – K130573) AccuLiF® TL-PEEK Cage and AccuLiF® TL and PL (CoALign Innovation – K112095)
Performance Data:	THE AUDERE Lumbar Spacer System has been tested in the following test modes: - Static axial compression per ASTM F2077 - Dynamic axial compression per ASTM F2077 - Expulsion per ASTM F-04.25.02.02 - Subsidence per ASTM F2267 The results of this non-clinical testing show that the strength of the AUDERE Lumbar Spacer System is sufficient for its intended use and substantially equivalent to legally marketed predicate devices.
Technological Characteristics:	The modified ADUERE Lumbar Spacer System possesses the same technological characteristics as one or more of the predicate devices. These include: - Performance (as described above), - Basic design (machined structural interbody) - Material (PEEK and Tantalum) and - Size (dimensions are comparable to those offered by the cleared devices) Therefore, the fundamental scientific technology of the modified AUDERE Lumbar Spacer System is the same as previously cleared devices.
Conclusion:	The modified AUDERE Lumbar Spacer System possesses the same intended use and technological characteristics as the predicate devices. Therefore, the modified ADUERE Lumbar Spacer System is substantially equivalent for its intended use.