December 17, 2018

Met One Technologies
% Mr. Daniel Johnson
Design Engineer
JALEX Medical, LLC
30311 Clemens Road, Suite 5D
Westlake, Ohio 44145

Re: K180772
Trade/Device Name: Met One Czar Anterior Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: November 16, 2018
Received: November 19, 2018

Dear Mr. Johnson:

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,

Ronald P. Jean -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)*
K180772

Device Name
Met One Czar Anterior Cervical Plate System

Indications for Use *(Describe)*
The system is indicated for use in the temporary stabilization of the anterior spine from C2 to T1 during the development of cervical spinal fusions in patients with: Degenerative Disc Disease, Trauma, Spinal Stenosis, Cervical myelopathy, Deformities or Curvatures, Tumor, Pseudoarthrosis, and failed previous fusion.

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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K180772 - 510(k) Summary

Submitted By:	Met One Technologies 154 N. Festival Dr. Villa F El Paso, TX 79912
Date:	03/23/2018
Contact Person:	Daniel Johnson, Design Engineer
Contact Telephone:	(440) 541-0060
Contact Fax:	(440) 933-7839
Device Trade Name:	Met One Czar Anterior Cervical Plate System
Device Classification Name:	Spinal Intervertebral Body Fixation Orthosis
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Product Code:	KWQ
Primary Predicate Device:	Stryker Aviator® Anterior Cervical Plating (ACP) System (K142237) The primary predicate device has never been subject to a recall.
Reference Predicate:	Interpore C-TEK Anterior Cervical Plate System (K041794) The reference predicate device has never been subject to recall.

Device Description:

The Met One Czar Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. The Met One Czar Anterior Cervical Plate System includes screws, plates, and a set of instruments to insert the implants. Plates are available in a variety of lengths to accommodate fusion procedures from one to four levels of the cervical spine. Fixation is achieved by inserting the screws through the openings in the plate into vertebral bodies of the cervical spine. Met One Czar plates are manufactured from Titanium 6Al-4V ELI per ASTM F136 and Invibio PEEK-OPTIMA™ LT1 per ASTM F2026.

Intended Use:

The system is indicated for use in the temporary stabilization of the anterior spine from C2 to T1 during the development of cervical spinal fusions in patients with: Degenerative Disc Disease, Trauma, Spinal Stenosis, Cervical myelopathy, Deformities or Curvatures, Tumor, Pseudoarthrosis, and failed previous fusion.

Summary of Technological Characteristics:

The Met One Czar Anterior Cervical Plate System and the predicate have the same intended use and fundamental scientific technology. Both devices compare similarly in:

- Design features
- Intended use
- Materials
- Dimensions
- Function

Mechanical Testing:

Substantial equivalence is supported by the results of mechanical testing including static and dynamic compression and static torsion per ASTM F1717.

Conclusion:

Based on the indications for use, technological characteristics, and comparison with the predicate device, the subject device has demonstrated substantial equivalence.