May 31, 2019

EiserTech, LLC
℅ Dawn Norman
Executive VP
MRC-X, LLC
6075 Poplar Ave
Memphis, Tennessee 38119

Re: K190565
Trade/Device Name: Cervical Plate
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: February 22, 2019
Received: March 5, 2019

Dear Dawn Norman:

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
CAPT Raquel Peat, PhD, MPH, USPHS
Director
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)*
K190565

Device Name
Cervical Plate

Indications for Use *(Describe)*
The Cervical Plate is intended for anterior screw fixation to the cervical spine (C2-C7) for immobilization and stabilization as an adjunct to fusion in skeletally mature patients for the following indications:

-Degenerative disc disease (DDD, defined as neck pain of discogenic origin with degenertion of the disc confirmed by history and radiographic studies)
-Spondylolisthesis
-Fracture
-Spinal stenosis
-Tumors (primary and metastatic)
-Failed previous fusions
-Pseudoarthrosis
-Deformity (i.e. kyphosis, lordosis, and/or scoliosis).

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
Cervical Plate
February 22, 2019

Company: Eistertech, LLC
9988 Hibert Street Suite 302
San Diego, CA 92131

Establishment Registration: 3009381326

Primary Contact: Dawn Norman
Phone: 618-604-3064

Company Contact: Lukas Eisermann
Phone: 888-262-2817

Trade Name: Cervical Plate

Common Name: Anterior Cervical Plate

Classification: Class II

Regulation Number: 21 CFR 888.3060 Spinal Intervertebral Body Fixation Orthosis

Panel: 87- Orthopedic

Product Code: KWQ

Primary Predicate Device: Eisertech,LLC Cervical Plate (K113170)

Device Description:
The Eisertech, LLC. Cervical Plate (K113170) is a spinal internal fixation device which is provided in a variety of sizes ranging from 20mm to 100mm in length. The device is designed to accommodate fusion of one to four levels of the cervical spine. Two screws may be affixed to each vertebral body associated with the spinal fusion. Instrumentation to facilitate implantation of the cervical plate is included with the device. This instrumentation is the subject of the present Traditional 510(k) submission. Specifically, the present Traditional 510(k) submission seeks to add two additional base material options as well as a surface treatment to all previously cleared instruments for use with the cervical plate system. The purpose of the surface treatment is to add scratch resistance and hydrophobicity to the instruments. *There are no changes to the implants and the surface treatment is not being applied to the implants.*

Indications for Use:
The Cervical Plate is intended for anterior screw fixation to the cervical spine (C2-C7) for immobilization and stabilization as an adjunct to fusion in skeletally mature patients for the following indications:

-Degenerative disc disease (DDD, defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
- Spondylolisthesis
- Fracture
- Spinal stenosis
- Tumors (primary and metastatic)
- Failed previous fusions
- Pseudoarthrosis
- Deformity (i.e. kyphosis, lordosis, and/or scoliosis).

Substantial Equivalence:
The subject Cervical Plate components are substantially equivalent to the following Primary Predicate device:

Eisertech, LLC Cervical Plate: K113170

The subject components are similar to the predicate devices in terms of indications, geometry, and materials. Biocompatibility and wear testing have confirmed that the addition of a surface treatment to all previously cleared instruments for use with the cervical plate system does not negatively impact the performance of the instruments. Thus, it can be concluded that the subject devices raise no new questions of safety and effectiveness and are substantially equivalent to the predicate devices.

Performance Testing:

Biocompatibility Testing was performed to ensure that the addition of a surface treatment to all previously cleared instruments for use with the cervical plate system does not negatively impact biocompatibility of the instruments. Additionally, ball on flat wear testing, instrumented indentation testing, and corrosion resistance testing was performed to demonstrate that the coating provides additional wear/corrosion resistance to the instruments.

Conclusion:

There are no substantial differences between the Cervical Plate and the predicate device with respect to intended use and technological characteristics, including basic design, base materials of manufacture, mechanical properties, and intended effect.

Therefore, the Cervical Plate can be found substantially equivalent to the cited predicate, as it does not raise new questions of safety and effectiveness.