December 26, 2019

EiserTech, LLC
℅ Dawn Norman
Executive Vice President
MRC/X, LLC
6075 Poplar Avenue
Memphis, Tennessee 38119

Re: K192768
Trade/Device Name: Temporary Fixation Pins
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: JDW, HTY
Dated: September 28, 2019
Received: September 30, 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,

Ronald P. Jean, Ph.D.
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)*

K192768

Device Name
Temporary Fixation Pins

Indications for Use *(Describe)*

Eisertech, LLC Temporary Fixation Pins are indicated for the following:
- guide wire for osteosynthesis implants
- accessories for external fixation (Steinmann Pin)
- application as implant according to the principles of fracture management

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Temporary Fixation Pin

September 28, 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:	Temporary Fixation Pin
Common Name:	Pin, Fixation, Smooth Pin, Fixation, Threaded
Classification:	Class II
Regulation Number:	21 CFR 888.3040 (Smooth or threaded metallic bone fixation fastener)
Panel:	87- Orthopedic
Product Code:	JDW, HTY
Primary Predicate Device:	aap Implantate AG aap Wire Bone / K-Wire; Cerciage Wire, Steinmann Pin (K131459)
Reference Predicate Device:	Eisertech, LLC Cervical Plate System Instruments (K190565)

Device Description:

The Eisertech, LLC Temporary Fixation Pins are indicated for the fixation of bone fractures, fusion of joints or bone reconstructions, or as guide pins for insertion of other implants. The Temporary Fixation Pins are offered in a variety of lengths, diameters, tip styles, and threading. The devices are made of either 17-4 stainless steel per ASTM F138 or titanium alloy (Ti-6Al-4V-ELI) per ASTM F136. The devices are delivered non-sterile and have to be sterilized before use. After fracture healing the implants have to be removed.

Indications for Use:
Eisertech, LLC Temporary Fixation Pins are indicated for the following:
- guide wire for osteosynthesis implants
- accessories for external fixation (Steinmann Pin)
- application as implant according to the principles of fracture management

Substantial Equivalence:
The subject Eisertech, LLC Temporary Fixation Pin is substantially equivalent to predicate aap Implantate AG's aap Wire Bone / K-Wire; Cerclage Wire, Steinmann Pin (K131459, S.E. 10/17/2013) with the surface treatment being identical to the surface treatment cleared for use in instruments in reference device Eisertech, LLC's Cervical Plate System Instruments (K190565, S.E. 05/31/2019).

The Indications for Use, Materials, and Geometry for predicate devices are all similar to those of the subject device. The surface treatment is identical to the surface treatment applied to the reference device Eisertech, LLC Cervical Plate Instruments.

Performance Testing:

The subject Temporary Fixation pins are manufactured from the same materials, fall within the geometry and dimensions, and share the same intended use as previously cleared for the predicate device. Therefore, it is expected that they would perform equivalent to the predicate devices. Thus, performance testing is not necessary and was not performed on the subject device.

Conclusion:

There are no substantial differences between the Temporary Fixation Pins 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 Temporary Fixation Pins can be found substantially equivalent to the cited predicate, as it does not raise new questions of safety and effectiveness.