DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 30, 2015

Eminent Spine
% Ms. Meredith May
Empirical Testing Corporation
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K143365
Trade/Device Name: Eminent Foot Plate Systems
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: February 20, 2015
Received: February 25, 2015

Dear Ms. May:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

Device Name
Eminent Foot Plate System

Indications for Use *(Describe)*

The Eminent Foot Plate System is intended for fixation of fractures, osteotomies, non-unions, revisions, replantations, of bones and bone fragments including tarsals, metatarsals, calcaneus, foot, and ankle.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.
DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.
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5. 510(K) SUMMARY

Submitter's Name:	Eminent Spine
Submitter's Address:	7200 N. IH 35 Bldg. #1 Georgetown, TX 78626
Submitter's Telephone:	512.868.5980
Contact Person:	Meredith L. May MS, RAC Empirical Consulting LLC 719.337.7579
Date Summary was Prepared:	04-Nov-14
Trade or Proprietary Name:	Eminent Foot Plate System
Common or Usual Name:	Single/multiple component metallic bone fixation appliances and accessories (§888.3030) Smooth or threaded metallic bone fixation fastener (§888.3040)
Classification:	Class II per 21 CFR §888.3030 Class II per 21 CFR §888.3040
Product Code:	HRS, HWC
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Eminent Foot Plate System consists of implants and instruments designed for fixation to treat fractures, deformations, revisions and replantations of bones and bone fragments. The system features twenty four (24) types of plates (Evans, Metatarsal, Metatarsal Left, Metatarsal Right, Metatarsal Step Left, Metatarsal Step Right, PMO Left, PMO Right, PMO Wedge Left, PMO Wedge Right, Osteotomy Left, Osteotomy Right, Osteotomy Wedge Left, Osteotomy Wedge Right, Osteotomy L Left, Osteotomy L Right, Peanut, Peanut Slotted, Utility, Utility Long, Lis' Franc, Calcaneus, Calcaneus Long, and Forefoot H), bone screws for fixation, and a set of instruments to facilitate installation and removal of the implants. The plates have screw holes, which allow for attachment to the bones or bone fragments. The plates are fabricated from medical grade titanium (ASTM F136), and offered in various widths and lengths. Plates and screws are provided non-sterile.

INDICATIONS FOR USE

The Eminent Foot Plate System is intended for fixation of fractures, osteotomies, non-unions, revisions, replantations, of bones and bone fragments including tarsals, metatarsals, calcaneus, foot, and ankle.

CONTRAINDICATIONS

Active or latent infection. Osteoporosis, insufficient quantity or quality of bone/soft tissue. Material sensitivity. If suspected, tests should be performed prior to implantation. Sepsis. Patients who are unwilling or incapable of following postoperative care instructions. This device

is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are similar between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structural support mechanism
- Principles of Operation

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Type**
K131722	Extremity Fixation Systems	I.T.S.	Primary
K071105, K091614, K131445, K133437	FPS – Foot Plate System	Osteomed	Additional

PERFORMANCE DATA

The Eminent Foot Plate System has been tested in the following test modes:

- Static Three-point Bending Test per ASTM F382
- Dynamic Three-point Bending Test per ASTM F382
- Torsion Testing per ASTM F543
- Static Axial Pullout Test per ASTM F543

The results of this non-clinical testing show that the strength of the Eminent Foot Plate System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Eminent Foot Plate System is substantially equivalent to the predicate device.