March 26, 2020

Gramercy Extremity Orthopedics, LLC
Michael P. Simpson
CEO
1239 N Glenville Dr.
Richardson, Texas 75081

Re: K200108
Trade/Device Name: GEO 1st MTP Joint Arthrodesis Plating System
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: January 10, 2020
Received: January 17, 2020

Dear Michael Simpson:

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,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*
K200108

Device Name
GEO 1st MTP Joint Arthrodesis Plating System

Indications for Use *(Describe)*

The GEO 1st MTP Joint Arthrodesis Plating System is indicated for use in the stabilization and fixation of the first metatarsal-phalangeal joint in the foot for surgical fusion (arthrodesis), osteotomy, nonunion, malunion or revision surgery.

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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GEO 1st MTP Joint Arthrodesis Plating System 510(k) Summary

Submitted by/ Sponsor:	Gramercy Extremity Orthopedics, LLC. 840 F. Avenue #104 Richardson, TX 75081 USA 972-908-9808	**Contact Person:**	Michael Simpson CEO 855-436-2278
Date Prepared:	March 24, 2020		
Trade Name:	GEO 1st MTP Joint Arthrodesis Plating System		
Common Name:	Plate, Fixation, Bone		
Classification Code Name & Reference:	HRS, HWC	Plate, Fixation, Bone	
	21 CFR §888.3030	Single/multiple component metallic bone fixation appliances and accessories.	
Predicate Devices	K041287: Vilex Plating System		

Device Description:
The GEO 1st MTP Joint Arthrodesis Plating System consists of anatomically contoured, low- profile plates in a variety of configurations of length, left and right versions, and degrees of dorsiflexion and abduction. The plates accept both fixed angle locking screws and non-locking screws. Fixed angle cortical locking screws are available in diameters of 2.7mm and 3.5. Non-locking cortical screws are available in 2.7mm, 3.5mm and 4.0mm; and non-locking cancellous screws in 4.0mm. All screws are offered in lengths of 10-40mm. The system also includes associated instrumentation consisting of plate tacks, guide-wire/k-wire, drill bit, drill guides (locking and non-locking), AO driver tip, reamers, depth gauge, non-locking drill guide handle, AO driver handle, and templates for plate and reamer sizing. All GEO 1st MTP Joint Arthrodesis Plating System components (implants and instruments) are provided sterile and for single use only.

Indications for Use:
The GEO 1st MTP Joint Arthrodesis Plating System is indicated for use in the stabilization and fixation of the first metatarsal-phalangeal joint in the foot for surgical fusion (arthrodesis), osteotomy, nonunion, malunion or revision surgery.

Technological Characteristics: The GEO 1st MTP plate and screw implants are comprised of titanium alloy Ti-6Al-4V conforming to ASTM F136-13 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications. All patient contacting components are comprised of biocompatible materials. All System components are provided sterile by gamma radiation and are disposable, for single-use only.

Comparison to Predicate
The GEO 1st MTP Joint Arthrodesis Plating System compares favorably to the predicate. The intended use is the same as that of the predicate, both are anatomically contoured for the 1st metatarsal phalangeal joint, comprised of the same material, utilize locking and non-locking screws, and adhere to the same testing standards. There are minor technological differences between the subject and predicate devices. The hole location and configuration is slightly different, and overall length range of the subject plates is slightly shorter than that of the predicate. The subject plates are offered in 0° and 5° of dorsiflexion/abduction whereas the predicate also offers 10°. The thickness of both subject and predicate plates is the same, but the subject plate is slightly thicker at the joint for added strength. The screw diameter offerings of the subject device are slightly different but within the range of the predicate. The GEO subject device is offered sterile, individually packaged whereas the subject device is provided non-sterile, requiring user performed cleaning and sterilization. These differences are considered to be minor and results of performance testing supports substantial equivalence.

Substantial Equivalence: The GEO 1st MTP Joint Arthrodesis Plating System is substantially equivalent to the Vilex Plating System cleared under K041287. The GEO 1st MTP Joint Arthrodesis Plating System has the same intended use and material as the predicate and the minor technological differences in plate and screw geometry (overall plate and screw lengths, plate hole placement/configuration and angulation, and overall screw lengths as described above) are not considered to raise new questions of safety or effectiveness.

Performance Data
Performance testing was performed on the GEO 1st MTP Joint Arthrodesis Plating System plates and screws in accordance with ASTM F382-17-17 Standard Specification and Test Methods for Metallic Bone Plates, and ASTM F543-17 Standard Specification and Test Methods for Metallic Medical Bone Screws. The results of performance testing demonstrate the GEO 1st MTP Joint Arthrodesis Plating System to be substantially equivalent to the predicate device.

Conclusion
The GEO 1st MTP Joint Arthrodesis Plating System is considered to be substantially equivalent to the predicate device. This conclusion is based on the similarities in principles of operation, technology, materials and intended use.