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

January 11, 2019

Re: K182212
Trade/Device Name: Geo Staple System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDR
Dated: December 13, 2018
Received: December 14, 2018

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/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,

Vesa Vuniqi -S

Digitally signed by Vesa Vuniqi -S
Date: 2019.01.11 21:21:09 -05'00'

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)*

K182212

Device Name
GEO STAPLE SYSTEM

Indications for Use *(Describe)*
The GEO Staple System is intended for fixation of small bone fragments, fixation of osteotomies, and joint arthrodesis.

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)

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GEO GRAMERCY EXTREMITY ORTHOPEDICS

GEO Staple System 510(k) Summary

Submitted by/ Sponsor:	Gramercy Extremity Orthopedics, LLC. 840 F. Avenue #104 Richardson, TX 75081 USA 972-908-9808	**Contact Person:**	Mary Biggers Regulatory Affairs 855-436-2278
Date Prepared:	August 14, 2018		
Trade Name:	GEO Staple System		
Common Name:	Staple, Fixation, Bone		
Classification Code Name & Reference:	JDR	Staple, Fixation, Bone	21 CFR §888.3030
Predicate Devices	Primary: K122113; Memory Metal Staples (Stryker Corporation) K112837: Vilex eZ-Staple Superelastic Bone Fixation Staple K141550: InstaFix™ Shape Memory Fixation System		

Device Description:
The GEO Staple System consists of symmetric and asymmetric, barbed and smooth, superelastic Nitinol alloy compression bone staples in varying lengths and widths. The System also includes associated instrumentation consisting of a staple inserter, drill guide, drill bit and locator pins. The nitinol implant material conforms to ASTM F2063-12 Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants. GEO Staples are offered in widths ranging from 8mm – 25mm. To facilitate implantation, GEO Staples are provided preloaded in the Staple Inserter. All GEO Staple System components (implants and instruments) are provided sterile and for single use only.

Indications for Use:
The GEO Staple System is intended for fixation of small bone fragments, fixation of osteotomies, and joint arthrodesis.

Technological Characteristics: The GEO Bone Staple System is comprised of Nitinol shape memory allow conforming to ASTM F2063-12 Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants. All System components are provided sterile by gamma irritation and are disposable, for single-use only. All patient contacting components are comprised of biocompatible materials.

Comparison to Predicate
The GEO Staple System compares favorably to the primary and additional predicates with regard to technological characteristics. The intended use is the same and the indications for use are within those of the primary predicate. Unlike the primary predicate, the GEO Staple is preloaded in a Staple/Inserter assembly, is includes barbed and smooth designs whereas the primary predicate has only barbed, the GEO Staples are not electropolished (in response to surgeon preference), and there are small dimensional differences in leg length. Though these technological characteristics are considered to raise new questions of safety or effectiveness, additional predicates were cited.

Substantial Equivalence: The GEO Staple System is substantially equivalent to the Stryker Corporation Easy Clip Memory Metal Staples [Primary Predicate] cleared under K122113. Additional predicates, Vilex eZ Staple [K112837] and OT Medical InstaFix Staples [K141550] are included for specific product features described above. The GEO Staples have the same intended use and material composition as the primary predicate and the technological differences are not considered to raise new questions of safety or effectiveness.

Performance Data

Performance testing was performed on the GEO Staples and predicate devices. The following testing was conducted in accordance with ASTM F564-17 Standard Specification and Test Methods for Metallic Bone Staples: static compression testing, fatigue testing, pullout testing of both barbed and smooth staples. Corrosion resistance testing was performed in accordance with ASTM F2129-17, Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices. Additionally, GEO Staples were subjected to a surface chemical composition evaluation.

The results of performance testing demonstrate the GEO Staples to be substantially equivalent to the predicate device.

Conclusion

Based on comparison of the GEO Staple System to the predicate device with regard to intended use, technological characteristics, and the results of performance testing, the GEO Staple System is substantially equivalent.