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

Gramercy Extremity Orthopedics, LLC
Ms. Mary Biggers
Regulatory Affairs
1239 N. Glenville Drive
Richardson, Texas 75081

January 18, 2017

Re: K161904
Trade/Device Name: GEO Bone Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: December 8, 2016
Received: December 12, 2016

Dear Ms. Mary Biggers:

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 and Part 809); 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 and Part 809), 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" (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 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,

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 below.

510(k) Number *(if known)*
K161904

Device Name

GEO BONE SCREW SYSTEM

Indications for Use *(Describe)*
The GEO Bone Screw System is indicated for bone fractures, osteotomies, arthrodesis, osteochondritis, and tendon reattachment.

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
K161904: GEO Bone Screw System

Submitted by:	Gramercy Extremity Orthopedics, LLC 1239 N. Glenville Drive Richardson, Texas 75081 855-436-2278	
Date Prepared:	January 17, 2017	
Contact Person:	Mary Biggers Regulatory Affairs 855-436-2278	
Trade Name:	GEO Bone Screw System	
Common Names:	Fixation bone screw	Washer, Bolt Nut
Classification Names:	Smooth or threaded metallic bone fixation fastener	Single/multiple, component metallic bone fixation appliances & accessories
References:	21 CFR § 888.3040 – Class II	21 CFR § 888.3030 – Class II
Product Codes:	HWC	HTN
Primary Predicate	K991151/K991197: Cannulated Screws (Vilex)	
Additional Predicates	K042310: Cannulated Bone Screws (OrthoPro) K143460: Cannulated Screw System (Wright Medical) K150693: PHIN-FX Cannulated Lag Screw System (Ascent Medical, LLC.)	
Device Description:	The GEO Bone Screw System implants include cannulated and solid, low-profile headed and headless, partial and fully threaded bone screws in a variety of diameters and lengths. Optional washers, correspondingly sized to each bone screw, are available as well as k-wires and general orthopedic instruments. GEO implants are comprised of titanium alloy. The GEO Bone Screw System is provided sterile by exposure to gamma irradiation.	
Indications for Use:	The GEO Bone Screw System is indicated for bone fractures, osteotomies, arthrodesis, osteochondritis, and tendon reattachment.	

510(k) Summary
K161904: GEO Bone Screw System

Technological Comparison:

The GEO Screw System has similar technical characteristics including indications for use, dimensions of diameter and length, material (titanium alloy) and basic design (threaded, cannulated and solid, self tapping, self drilling) as the legally marketed predicate devices.

Performance Data:

An engineering analysis was performed for torsional strength and pullout strength for worst case GEO bone screws and comparable worst case predicate bone screws. This analysis showed the GEO Bone Screw results to be equivalent or better than that of the predicate. Pyrogenicity (LAL) testing was conducted on worst case bone screw/washers using the gel-clot method. The results from the pyrogen testing show the EU levels below the limit. Based on these data, the GEO Bone Screws have the design, geometry and mechanical properties suitable for performing its intended use.

No clinical performance data were needed to support substantial equivalence.

Summary:

The GEO Bone Screw System is substantially equivalent to the predicate devices based upon the indication for use, technological characteristics, and the data submitted.