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

Re: K202817
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: August 31, 2020
Received: September 24, 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,

For; 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202817

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. Surgical indications include fixation of malunion and nonunion, acute fractures, repetitive stress fractures, malleolar, talus, and greater tuberosity fractures, Jones fracture and 5th metatarsal fracture fixation and bone reconstruction where appropriate for the size of the device.

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
GRAMERCY
EXTREMITY ORTHOPEDICS

510(k) Summary GEO Bone Screw System			
Submitted by:	Gramercy Extremity Orthopedics 1239 N. Glenville Drive Richardson, TX 75081	**Contact Person:**	Michael Simpson, CEO 855-436-2278
		Date Prepared:	August 31, 2020
Trade Name:	GEO Bone Screw System		
Predicate	Primary Predicate Device (self): K161904 GEO Bone Screw System Additional Predicate Devices: K153154 Stryker Asnis JFX System, K190686 Paragon 28 Monster Screw System, K191289 Vilex Bone Screw Line Addition, K180377 In2Bones Fracture and Correction 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	
Regulation:	21 CFR 888.3040	21 CFR 888.3030	
Classification	II	II	
Product Codes	HWC	HTN	

Device Description:
The GEO Bone Screw System consists of sterile, stand-alone headed and headless, cannulated and solid, threaded bone screws, washers, and instrumentation. Bone screws are available in a variety of diameters and lengths including partially and fully threaded designs to accommodate application in varying bone sizes (for the Jones Fracture / 5th metatarsal procedures only the 4.0mm-6.5mm diameter screws are appropriate). Optional washers are available and sized to correspond with bone screws. K-wires and general, manual orthopedic instrumentation is provided and intended to facilitate implantation. Instrumentation includes wire guides, guide handles, AO drive handles, drill bits, taps, depth gauges, countersinks, tissue protectors, hexalobe driver tips and screw diameter templates. GEO implants are comprised of titanium alloy. All implants and instruments are provided for single use only and sterilized by exposure to gamma irradiation.

Indications for Use:
The GEO Bone Screw System is indicated for bone fractures, osteotomies, arthrodesis, osteochondritis, and tendon reattachment. Surgical indications include fixation of malunion and nonunion, acute fractures, repetitive stress fractures, malleolar, talus, and greater tuberosity fractures, Jones fracture and 5th metatarsal fracture fixation and bone reconstruction where appropriate for the size of the device.

Technical Comparison & Equivalence:
The GEO Bone Screw System subject device has the same design and technological features as the cleared, commercially distributed predicate GEO Bone Screw System (K161904). The labeling has been revised to include examples of surgical indications within the cleared intended use of the device. No new questions of safety and effectiveness are raised by this modification.

Performance Data:
No additional performance testing was required. The GEO Bone Screw System components have been subjected to design controls and previously tested to appropriate device-specific standards to support substantial equivalence, and validation to standards necessary to demonstrate the functionality of the device system.

Summary: The GEO Bone Screw System described herein is substantially equivalent to the predicate device (original GEO Bone Screw System) based upon the intended use, technological characteristics.

Conclusion

The GEO Bone Screw System with revised indications for use is substantially equivalent to the predicate device.