December 17, 2019

G Surgical LLC
% Karen E. Warden, PhD
President
BackRoads Consulting Inc.
PO Box 566
Chesterland, Ohio 44026

Re: K193219
Trade/Device Name: G Surgical Marksman System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: November 20, 2019
Received: November 21, 2019

Dear Dr. Warden:

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,

Colin O’Neill, MBE
Assistant Director (Acting)
DHT6B: Division of Spinal 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)*

K193219

Device Name
G Surgical Marksman System

Indications for Use *(Describe)*

The G Surgical Marksman System is intended to provide immobilization and stabilization of the posterior non-cervical spine (T1-S2/Ilium) in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis and/or lordosis), tumor, pseudarthrosis, and/or failed previous fusion.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 7 – 510(k) Summary

Date:	20 November 2019
Sponsor:	G Surgical LLC 9433 Bee Cave Road Building 3, Suite 101-A Austin, Texas 78733 USA Tel.: 512.494.4749
Sponsor Contact:	Don Grafton, Managing Director
510(k) Contact:	Karen E. Warden, PhD BackRoads Consulting Inc. PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Proposed Trade Name:	G Surgical Marksman System
Common Name:	Posterior pedicle screw system
Device Classification:	Class II
Regulation Name, Regulation Number, Product Code:	Thoracolumbosacral pedicle screw system, 888.3070, NKB
Submission Purpose:	The subject 510(k) adds modified pedicle screws, rods, crosslinks and fasteners to the cleared components of the Marksman System.
Device Description:	The G Surgical Marksman MIS System consists of longitudinal members (rods), anchors (screws), connectors (crosslinks) and fasteners in a variety of sizes to accommodate differing anatomic requirements.
Indications for Use:	The G Surgical Marksman System is intended to provide immobilization and stabilization of the posterior non-cervical spine (T1-S2/Ilium) in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis and/or lordosis), tumor, pseudarthrosis, and/or failed previous fusion.
Materials:	G Surgical Marksman System is manufactured from Ti-6Al-4V ELI titanium alloy (ASTM F136) and Cobalt Chrome (per ASTM F1537).
Primary Predicate:	G Surgical Marksman MIS System (G Surgical LLC – K161516)
Additional Predicates:	G Surgical Pedicle System (G Surgical LLC – K081041), Tiger® Spine System (CoreLink LLC – K133369), Moss Miami™ Spinal System (DePuy AcroMed, Inc. – K022623) and Optima™ Spinal System (U&I Corporation – K051971)
Performance Data:	Mechanical testing of worst case G Surgical Marksman System constructs included static and dynamic compression bending and static torsion according to ASTM F1717. The mechanical test results demonstrate that G Surgical Marksman System performance is substantially equivalent to the predicate devices.

Technological Characteristics:

The G Surgical Marksman System possesses the same technological characteristics as one or more of the predicate devices. These include:

- intended use (as described above)
- basic design (rod and screw configuration),
- material (titanium alloy) and
- sizes (dimensions are comparable to those offered by the predicate systems)

The fundamental scientific technology of the G Surgical Marksman System is the same as previously cleared devices.

Conclusion:

The G Surgical Marksman System possesses the same intended use and technological characteristics as the predicate devices. Therefore G Surgical Marksman System is substantially equivalent for its intended use.