



April 5, 2024

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

Re: K240737

Trade/Device Name: G Surgical Marksman MIS System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: March 18, 2024
Received: March 18, 2024

Dear Karen 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S



Colin O'Neill, M.B.E.

Assistant Director

DHT6B: Division of Spinal Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K240737

Device Name

G Surgical Marksman MIS System

Indications for Use (Describe)

The G Surgical Marksman MIS 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. The G Surgical Marksman MIS System can be used in an open approach or a percutaneous approach with MIS instrumentation.

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

Date: 18 March 2024

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 MIS 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 long arm polyaxial screws and a larger diameter screw to the cleared components.

Device Description: The G Surgical Marksman MIS System consists of longitudinal members (rods), anchors (screws) and fasteners in a variety of sizes to accommodate differing anatomic requirements. The devices are sold nonsterile.

Indications for Use: The G Surgical Marksman MIS 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. The G Surgical Marksman MIS System can be used in an open approach or a percutaneous approach with MIS instrumentation.

Materials: G Surgical Marksman MIS 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)

Performance Data: ASTM F1717 mechanical testing of worst case G Surgical Marksman MIS System constructs was relied upon in support of this G Surgical Marksman MIS clearance. The testing included static and dynamic compression bending and static torsion.

Technological Characteristics: The G Surgical Marksman MIS System is identical to itself as the primary predicate with respect to the following technological characteristics: basic design, material and dimensional features.

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