December 19, 2017

G Surgical LLC
% Karen E. Warden, Ph.D.
President
BackRoads Consulting, Inc.
P.O. Box 566
Chesterland, Ohio 44026-2141

Re: K171834
Trade/Device Name: G Surgical OCT Spinal System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: November 24, 2017
Received: November 28, 2017

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. 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); 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.

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.

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,

Ronald P. Jean -S 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)*
K171834

Device Name
G Surgical OCT Spinal System

Indications for Use *(Describe)*
The G Surgical OCT Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, cervical spine (C1 to C7) and the thoracic spine (T1 to T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The G Surgical OCT Spinal System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the G Surgical OCT Spinal System may be connected to the G Surgical Pedicle System (GPS™) using 3.5mm/6.0mm axial connectors, domino connectors and transition rods.

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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510(k) Summary

Date:	16 June 2017
Sponsor:	G Surgical LLC 9433 Bee Cave Road Building 3, Suite 101-A Austin, Texas 78733 USA Tel.: 512.494.4749
Contact Person:	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 OCT Spinal System
Common Name:	Posterior occipital-cervical-thoracic system
Device Classification	Class II
Classification Name; Regulation; Device Product Code:	Orthosis, Cervical Pedicle Screw Spine Fixation; Pre-amendment; NKG Appliance, Fixation, Spinal Interlaminal: 888.3050; KWP
Device Description:	G Surgical OCT Spinal System consists of longitudinal members, anchors, interconnecting devices and fasteners in a variety of sizes to accommodate differing anatomic requirements. The implants are sold non-sterile.
Intended Use:	The G Surgical OCT Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, cervical spine (C1 to C7) and the thoracic spine (T1 to T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The G Surgical OCT Spinal System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, the G Surgical OCT Spinal System may be connected to the G Surgical Pedicle System (GPS™) using 3.5mm/6.0mm axial connectors, domino connectors and transition rods.
Materials:	The G Surgical OCT Spinal System is manufactured from Ti-6Al-4V ELI titanium alloy (ASTM F136).
Primary Predicate	Synapse OCT (DePuy Synthes Spine – K142838)
Additional Predicates:	Virage OCT Spinal System (Zimmer Spine Inc. – K153631) CerviFix StarLock System (Synthes USA – K994187) Uniplate Anterior Cervical Plate (DePuy Spine – K042544)
Performance Data:	Mechanical testing of worst case G Surgical OCT Spinal System constructs included static and dynamic compression bending and static torsion according to ASTM F1717 and static and dynamic compression bending and torsion according to ASTM F2706. The mechanical test results demonstrate that G Surgical OCT Spinal System performance is substantially equivalent to the predicate devices.

Technological Characteristics:

The G Surgical OCT Spinal System possesses similar technological characteristics as the predicate devices. These include:

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

Therefore the fundamental scientific technology of the G Surgical OCT Spinal System is the same as previously cleared devices.

Conclusion:

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