April 23, 2021

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

Re: K210890
Trade/Device Name: GPS™ Cervical Spacers
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: March 24, 2021
Received: March 25, 2021

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,

Brent Showalter, Ph.D.
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

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)*

K210890

Device Name

GPS™ Cervical Spacers

Indications for Use *(Describe)*

The GPS™ Cervical Spacers are indicated for use at multiple contiguous levels, from C2-T1, in skeletally mature patients who have had six weeks of non-operative treatment. The device is intended to treat cervical disc degeneration and/or cervical spinal instability as confirmed by imaging studies (radiographs, CT, MRI) that results in radiculopathy, myelopathy and/or pain. The device is to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and in combination with supplemental fixation cleared for use in the cervical spine.

Type of Use *(Select one or both, as applicable)*

[X] 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:	24 March 2021
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:	GPS™ Cervical Spacers
Common Name:	Interbody fusion device
Device Classification:	Class II
Regulation Name, Regulation Number, Product Code:	Intervertebral body fusion device, 21 CFR 888.3080, ODP
Submission Purpose:	The subject 510(k) expands the product offering by adding a non-sterile implant option. In addition, the Indications for Use statement has been revised to expand usage from one to multiple contiguous levels and to add allogeneic bone graft.
Device Description:	The basic shape of the GPS™ Cervical Spacers is a structural column having upper and lower implant openings and a central cavity for autograft bone. The devices have a have a "B" shaped cross-section. Surface teeth assist in the seating the implant between the vertebral bodies. Devices are available in a variety of size and angulation combinations to accommodate the diversity in patient anatomy.
Indications for Use:	The GPS™ Cervical Spacers are indicated for use at multiple contiguous levels, from C2-T1, in skeletally mature patients who have had six weeks of non-operative treatment. The device is intended to treat cervical disc degeneration and/or cervical spinal instability as confirmed by imaging studies (radiographs, CT, MRI) that results in radiculopathy, myelopathy and/or pain. The device is to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and in combination with supplemental fixation cleared for use in the cervical spine.
Materials:	The GPS™ Spacers are manufactured from polyetheretherketone (PEEK) per ASTM F2026 (VESTAKEEP® i4 R, Evonik Polymers Technologies GmbH). Integral marker pins are manufactured from tantalum according to ASTM F560.
Primary Predicate:	GPS™ Spacers (G Surgical LLC – K142456)
Performance Data:	No new mechanical testing was performed for the GPS™ Cervical Spacers because the non-sterile condition does not create a mechanical worst case with respect to performance. Performance data remains unchanged for the subject devices as compared to the predicate versions of the device.

Technological Characteristics:

The GPS™ Cervical Spacers possess the same technological characteristics as the sterile versions of themselves. These include:

- perfromance (as described above),
- basic design (hollow structural frame),
- material (PEEK polymer and tantalum) and
- sizes (identical to those previously cleared)

The fundamental scientific technology of the GPS™ Spacers is the same as previously cleared devices.

Conclusion:

The GPS™ Cervical Spacers possess the same intended use and technological characteristics as the predicate devices. Therefore GPS™ Spacers are substantially equivalent for their intended use.