DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 5, 2017

SurgTech Inc.
% Karen E. Warden, Ph.D.
President
BackRoads Consulting Inc.
P.O. Box 566
Chesterland, Ohio 44026

Re: K163363
Trade/Device Name: SurgTech Thoracolumbosacral (TLS) Posterior Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: March 27, 2017
Received: March 29, 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163363

Device Name
SurgTech Thoracolumbosacral (TLS) Posterior Fixation System

Indications for Use *(Describe)*
The SurgTech Thoracolumbosacral (TLS) Posterior Fixation System is intended to provide pedicle and non-pedicle 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.

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510(k) Summary

Date:	23 March 2017
Sponsor:	SurgTech Inc. 24600 Center Ridge Road, Suite 195 Westlake, OH 44145 Phone (216) 421-2613
Sponsor Contact:	Xuegong Yu, General Manager
510(k) Contact:	Karen E. Warden, PhD BackRoads Consulting Inc. PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Proposed Trade Name:	SurgTech Thoracolumbosacral (TLS) Posterior Fixation System
Common Name:	Posterior pedicle screw and hook system
Regulatory Class:	Class II
Regulation Name, Regulation Number, Product Code(s):	Thoracolumbosacral pedicle screw system, 21 CFR 888.3070, NKB Spinal interlaminal fixation orthosis, 21 CFR 888.3050, KWP
Device Description:	The SurgTech Thoracolumbosacral (TLS) Posterior Fixation System consists of longitudinal members (rods), anchors (hooks and screws), interconnections (cross connector) and fasteners in a variety of sizes to accommodate differing anatomic requirements.
Indications for Use:	The SurgTech Thoracolumbosacral (TLS) Posterior Fixation System is intended to provide pedicle and non-pedicle 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:	SurgTech TLS System is manufactured from titanium alloys (Ti-6Al-4V ELI per ASTM F136 and Ti-6Al-7Nb per ASTM F1295).
Primary Predicate:	CD Horizon® Spinal System (Medtronic Sofamor Danek – K152457)
Additional Predicates:	Matrix Spine System (Synthes Spine – K092929), Moss Miami™ Spinal System (DePuy AcroMed, Inc. – K022623) and Optima™ Spinal System (U&I Corporation – K051971)
Performance Data:	Mechanical testing of worst case SurgTech TLS System constructs included static and dynamic compression bending and static torsion according to ASTM F1717. The mechanical test results demonstrate that SurgTech TLS System performance is substantially equivalent to the predicate devices.

Technological Characteristics:

The SurgTech TLS 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/hook configuration),
- material (titanium alloy) and
- sizes (dimensions are comparable to those offered by the predicate systems)

The fundamental scientific technology of the SurgTech TLS System is the same as previously cleared devices.

Conclusion:

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