DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 25, 2016

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

Re: K152200
Trade/Device Name: SurgTech Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: March 11, 2016
Received: March 14, 2016

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 Parts 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" (21CFR 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 yours,

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)*
K152200

Device Name
SurgTech Interbody System

Indications for Use *(Describe)*
The SurgTech Interbody System is indicated for use with autogenous bone graft in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These patients may have had a previous non-fusion spinal surgery and may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved spinal level(s). These devices are intended to be used with supplemental fixation which has been cleared for use in the lumbar spine.

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:	5 August 2015
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
Trade Name:	SurgTech Interbody System
Common Name:	Interbody fusion device
Device Classification	Class II
Classification Name:	Intervertebral body fusion device
Regulation:	888.3080
Device Product Code:	MAX
Device Description:	The SurgTech Interbody System is a system of intervertebral body fusion devices. The Posterior Lumbar device is a structural column in a generally rectangular shape having a rounded nose. Teeth are integral to the inferior and superior surfaces and there is a central cavity to be filled with autograft. The implants are available in an assortment of footprint, height and angulation combinations to accommodate a variety of anatomic requirements.
Indications for Use:	The SurgTech Interbody System is indicated for use with autogenous bone graft in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These patients may have had a previous non-fusion spinal surgery and may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved spinal level(s). These devices are intended to be used with supplemental fixation which has been cleared for use in the lumbar spine.
Materials:	The SurgTech Interbody System cages are manufactured from PEEK Optima® LT1 (polyetheretherketone) per ASTM F2026 and contain tantalum radiopaque markers per ASTM F560.
Primary Predicate:	PLIF Cage (Eisertech LLC, K113478)
Additional Predicate:	AVS® PL PEEK Spacers (Stryker Spine – K073470, K082014 & K093704)
Performance Data:	Mechanical testing of the worst case SurgTech Interbody System device was performed according to ASTM F2077 and included static and dynamic compression. Subsidence testing according to ASTM F2267 was performed on the worst case SIS PL device. The mechanical test results demonstrate that the SurgTech Interbody System performance is substantially equivalent to the predicate devices.

Technological Characteristics:

The SurgTech Interbody System implants possess similar technological characteristics as one or more of the predicate devices. These include:

- performance (as described above),
- basic design (hollow structural column),
- implant grade materials (PEEK polymer and tantalum), and
- sizes (widths, lengths, heights and angulation are within the range(s) offered by the predicates).

Therefore the fundamental scientific technology of the SurgTech Interbody System is similar to previously cleared devices.

Conclusion:

The SurgTech Interbody System possesses similar intended use and technological characteristics as the predicate devices. Therefore SurgTech Interbody System is substantially equivalent to legally marketed predicates.