DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 21, 2017

SurgTech Inc
Karen E. Warden, Ph.D.
President
Backroads Consulting Inc.
PO Box 566
Chesterland, Ohio 44026-0566

Re: K161894
Trade/Device Name: SurgTech Trauma System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HRS
Dated: January 23, 2017
Received: January 25, 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 on last page.

510(k) Number *(if known)*
K161894

Device Name
SurgTech Trauma System

Indications for Use *(Describe)*

The SurgTech Trauma System plates and screws are intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions appropriate for the size and design of the device.
The large plate set components are indicated for the use in various long bones including the femur and tibia. The small plate set is indicated for use in various bones including the clavicle, scapula, humerus, radius, radius, ulna, pelvis, tibia and fibula. The mini plate set is indicated for use in various small bones including the metacarpals, metatarsals, phalanges, calcaneus and those of the ankle.

In addition, the SurgTech Trauma System cancellous, cannulated lag, headless compression and non-locking cortical screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation, appropriate for the size of the device.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date:	14 February 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
Trade Name:	SurgTech Trauma System
Common Name:	Bone plates & screws, Bone screws
Device Classification	Class II
Classification Name:	Smooth or threaded metallic bone fixation fastener & Single/multiple component metallic bone fixation accessories
Regulation:	888.3040, 888.3030
Device Product Code:	HWC, HRS
Device Description:	The SurgTech Trauma System is a plate and screw fixation system. Plates are offered in “mini,” “small” and “large” set sizes in a variety of shapes based upon the anatomical fixation required. Screws are also offered in “mini” “small” and “large” sets and, in addition, in locking cortical, non-locking cortical, cancellous and headless versions. Screws can also be used for fixation without the plates.
Indications for Use:	The SurgTech Trauma System plates and screws are intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions appropriate for the size and design of the device. The large plate set components are indicated for the use in various long bones including the femur and tibia. The small plate set is indicated for use in various bones including the clavicle, scapula, humerus, radius, radius, ulna, pelvis, tibia and fibula. The mini plate set is indicated for use in various small bones including the metacarpals, metatarsals, phalanges, calcaneus and those of the ankle. In addition, the SurgTech Trauma System cancellous, cannulated lag, headless compression and non-locking cortical screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation, appropriate for the size of the device.
Materials:	The SurgTech Trauma System implants are manufactured from titanium alloys (Ti6Al4V per ASTM F136 and Ti6Al7Nb per ASTM F1295) and stainless steel (ASTM F138).
Primary Predicate (plate & screw system):	GPC Bone Plates and Bone Screws (GPC Medical K092493)

Additional Predicates (plate & screw system):	The NCB Periprosthetic Femur Polyaxial Locking Plate System (Zimmer Inc. K100111), I.T.S. Straight Plate (I.T.S. GmbH K060156), I.TS. Volar Radius Plate (I.T.S. GmbH K033756), I.T.S. Olecranon Plate (I.T.S. GmbH K052368), Synthes Variable Angle LCP Elbow System (Synthes, K120070), I.T.S. Distal Humeral Plates (I.T.S. GmbH K080184), I.T.S. Straight Plate (I.T.S. GmbH K060156), I.T.S. Claviculatplate (I.T.S. GmbH K050852), Synthes (USA) Clavicle Hook Plate (Synthes, K031677), Synthes (USA) LCP® Proximal Humerus Plates (Synthes K041860), the I.T.S. Pelvic Reconstruction System (I.T.S. GmbH K063166), I.T.S. Fibula Plate (I.T.S. GmbH K063672), DePuy ALPS (DePuy Orthopaedics K082300), Acumed Hand Fracture System (Acumed LLC K141383), Synthes Locking Calcaneal Plates (Synthes K991407), I.T.S. Calcaneus Repair System (I.T.S. GmbH K051642), Synthes 2.4 mm / 2.7 mm Variable Angle (VA), - LCP Forefoot /Midfoot System (Synthes K100776) and Medartis APTUS® Foot System (Medartis K091479), Synthes Titanium Small Reconstruction Plate (Synthes K915818), Synthes Large Fragment Dynamic Compression Locking (DCL) System (Synthes K000682), Synthes Small Fragment Dynamic Compression Locking (DCL) (System K000684), 1.5mm Mini Fragment LCP System (Synthes K090047).
Primary Predicate (standalone screws):	OsteoMed Headless Cannulated Screw System (OsteoMed LP K063298)
Additional Predicates (standalone screws):	Treu Bone fixation Screws and Pins (Treu Instrumente GmbH K083912), Synthes Cortical Screws (Synthes K112583), Synthes 3.0 mm Headless Compression Screws (Synthes K050636), Synthes 4.5 mm and 6.5 mm Headless Compression Screws (Synthes K080943), Vilex Bone Screw (Vilex K014154), Synthes 7.0/7.3 mm Cannulated Screws (Synthes K962011), SBi Foot and Ankle Cannulated Screws (Small Bone Innovations K092754)
Performance Data:	Mechanical testing of the worst case SurgTech Trauma System plates included static and dynamic bending performed according to ASTM F382. Mechanical testing of the worst case SurgTech Trauma System screws included torsion, insertion/removal and pullout performed according to ASTM F543. Dimensional and theoretical comparisons demonstrated that the mechanical performance of the SurgTech Trauma System is substantially equivalent to the predicate devices.
Technological Characteristics:	The SurgTech Trauma System implants possess technological characteristics similar to one or more of the cited predicate devices. These include: • Mechanical performance (as described above), • Basic design (bone plate & screw system), • Use of implant grade materials (titanium, titanium alloys & stainless steel), and • Dimensional sizes (comparable to those offered by the predicates). Minor dimensional differences between the subject and predicate devices, such as longer or shorter device lengths, did not raise new questions of safety and effectiveness. Therefore the fundamental scientific technology of the SurgTech Trauma System is the same as previously cleared devices.
Conclusion:	The SurgTech Trauma System possesses the same intended use and similar indications for use compared to the cited predicates. The SurgTech Trauma System technological characteristics are similar to those of the cited predicate devices. Therefore SurgTech Trauma System is substantially equivalent for its intended use.