August 1, 2019

SurgTech, Inc.
% Kellen Hills
Quality and Regulatory Consultant
Orchid Design
80 Shelton Technology Center
Shelton, Connecticut 06484

Re: K191192
Trade/Device Name: SurgTech GENOLL™ Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: April 29, 2019
Received: May 3, 2019

Dear Kellen Hills:

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,

For CAPT Raquel Peat, PhD, MPH, USPHS
Director
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)*

K191192

Device Name

SurgTech GENOLL™ Total Knee System

Indications for Use *(Describe)*

The SurgTech GENOLL™ system is intended to reduce or relieve pain and restore function and motion to the knee joint. Total knee replacement is indicated for patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. This device may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery. This device is intended for cemented use only.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

[As Required by 21 CFR 807.92]

(a)(1)	Date Prepared:	April 29, 2019
	Submitted By:	SurgTech, Inc. 24600 Center Ridge Road, Suite 195 Westlake, OH 44145
	Phone:	440-899-2922
	Contact:	Robert Gutierrez
	Prepared By:	Orchid Design 80 Shelton Technology Center, Shelton, CT 06484
	Phone:	(203) 922 0105
(a)(2)	Proprietary Name:	SurgTech GENOLL™ Total Knee System
	Common Name:	Total Knee Prosthesis
	Classification Name and Reference:	21CFR 888.3560 - Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
	Product Code:	JWH
(a)(3)	Predicate Devices:	
	Primary:	Zimmer-NexGen LPS Flex (K991581);
	Additional:	Otis Biotech-Prolixus (K170534);
	Reference:	SurgTech-MALUC (K162125);

(a)(4) Device Description:

The SurgTech GENOLL™ Total Knee System is used for total knee arthroplasty in skeletally mature individuals. The system consists of a CoCr alloy Posterior Stabilized (PS) femoral component (10 sizes, Left and Right), a CoCr alloy tibial baseplate (10 sizes), a conventional polyethylene PS tibial bearing insert (5 sizes with 5 thicknesses each) and a conventional polyethylene patella (3 sizes). Instrumentation necessary for proper implantation is also included.

The purpose of this submission is to gain initial marketing authorization in the United States.

(a)(5) Indications for Use:

The SurgTech GENOLL™ system is intended to reduce or relieve pain and restore function and motion to the knee joint. Total knee replacement is indicated for patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary

traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. This device may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery. This device is intended for cemented use only.

(a)(6) Comparison of Technological Characteristics:
The SurgTech GENOLL Total Knee System is substantially equivalent to the previously cleared predicate devices based on similarities in intended use, design, materials, packaging, sterilization and mechanical performance. The technological characteristics do not raise any new questions of safety and efficacy.

(b)(1) Non-clinical testing:
The subject devices were evaluated for the following performance characteristics:

- Baseplate Fatigue (ASTM F1800)
- Constraint (ASTM F1223)
- Contact Area (ASTM F2083, ASTM F1672)
- PS Post Fatigue (ASTM F1814)
- Tibial Insert/Baseplate Disassembly (ASTM F2083, ASTM F1814)
- Bacterial endotoxins (USP <85>)

(b)(2) Clinical testing:
Clinical testing was not required to demonstrate substantial equivalence in this premarket notification.

(b)(3) Conclusions:
Based on the information provided in this premarket notification, we believe that the subject SurgTech GENOLL Total Knee System demonstrates substantial equivalence to the identified predicate devices.