June 14, 2018

SurgTech, Inc.,
% Kellen Hills
Quality and Regulatory Consultant
Orchid Design
4600 E Shelby Drive
Memphis, Tennessee 38118

Re: K173455
Trade/Device Name: SurgTech Bipolar Head System
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip Joint Femoral (Hemi-Hip) Metal/Polymer Cemented Or Uncemented Prosthesis
Regulatory Class: Class II
Product Code: KWY
Dated: May 2, 2018
Received: May 7, 2018

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. 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173455

Device Name

SurgTech Bipolar Head System

Indications for Use *(Describe)*
The SurgTech Bipolar Head system is intended for use for cases of:

• Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli and painful hip dysplasia.

• Inflammatory degenerative joint disease such as rheumatoid arthritis.

• Correction of function deformity.

• Revision procedures where other treatments or devices have failed.

• Treatment of nonunion femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

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.

510(k) Summary

[As Required by 21 CFR 807.92]

(a)(1)	Submitted By:	SurgTech, Inc. 24600 Center Ridge Road, Suite 195 Westlake, OH 44145
	Phone:	440-899-2922
	Date:	June 8, 2018
	Contact Persons	
	Primary:	Kellen Hills (Orchid Design Consulting) 901-433-1990
	Secondary:	Brian Hewko (SurgTech, Inc.)
(a)(2)	Proprietary Name:	SurgTech Bipolar Head System
	Common Name:	Bipolar Hip Prosthesis
	Classification Name and Reference:	21CFR 888.3390 - Hip Joint femoral (Hemi-Hip) Metal/Polymer Cemented or Uncemented Prosthesis
	Product Code:	KWY
(a)(3)	Predicate Devices:	
	Primary:	J&J ORTHOPAEDICS-PFC BIPOLAR (K931655)
	Additional:	United Orthopedic-U2 BIPOLAR (K152439);
	Additional:	Stryker-UHR Bipolar (K800207);
	Additional:	Howmedica – CENTRAX (K855231)
	Reference:	SurgTech-MALUC (K162125);

*No predicate has been subject to a design related recall.

(a)(4) Device Description:

The SurgTech Bipolar Head System is used for hip hemiarthroplasty in skeletally mature individuals. The system consists of a CoCr alloy shell (38-58mm outer diameters), a polyethylene bearing insert (22mm and 28mm inner diameters) and retaining ring, and CoCr alloy femoral heads (22mm and 28mm) in various offsets. Instrumentation necessary for proper implantation is also included.

28mm femoral heads as well as all femoral stems used in conjunction with the SurgTech Bipolar Head System were cleared previously in K162125.

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

(a)(5) Indications for Use:

The SurgTech Bipolar Head system is intended for use for cases of:

- Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli and painful hip dysplasia.
- Inflammatory degenerative joint disease such as rheumatoid arthritis.
- Correction of function deformity.
- Revision procedures where other treatments or devices have failed.

- Treatment of nonunion femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

(a)(6) Comparison of Technological Characteristics:
The SurgTech Bipolar Head 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:

- Femoral Head/Bipolar Liner Pull Out/Lever Out
- Femoral Head/Femoral Stem Pull Off
- Range of Motion
- Bacterial endotoxins

(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 Bipolar Head system demonstrates substantial equivalence to the identified predicate devices.