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

May 10, 2017

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

Re: K162125
Trade/Device Name: MALUC™ Total Hip Arthoplasty System
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JDI, LPH, LZO
Dated: April 7, 2017
Received: April 11, 2017

Dear Mr. 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.

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)*

K162125 (Page 1 of 1)

Device Name

MALUC™ Total Hip Arthroplasty System

Indications for Use *(Describe)*

The SurgTech MALUC™ System is intended for use for cases of severely painful and or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis or congenital hip dysplasia, avascular necrosis of the femoral head, acute traumatic fracture of the femoral head or neck, failed previous hip surgery (including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty and/or total arthroplasty), and certain cases of ankylosis.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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)	Submitted By:	SurgTech, Inc. 24600 Center Ridge Road, Suite 195 Westlake, OH 44145
	Phone:	901-433-1990
	Fax:	901-433-1989
	Date:	April 7, 2017
	Contact Persons	
	Primary:	Kellen Hills (Orchid Design Consulting)
	Secondary:	Brian Hewko (SurgTech, Inc.)
(a)(2)	Proprietary Name:	MALUC™ Total Hip Arthroplasty System
	Common Name:	Total Hip Prosthesis
	Classification Name and Reference:	21CFR 888.3350, 888.3358, 888.3353
	Product Code:	JDI, LPH, LZO
(a)(3)	Predicate Devices:	
	Primary:	DePuy SUMMIT (K023453);
	Additional:	Stryker Exeter V40 (K011623); Stryker Accolade TMZF (K032300); Stryker Trident (K040412, K991952, K022077, K010757, K070885); Depuy PINNACLE with GVF Liner (K000306);

(a)(4) Device Description:

The MALUC™ Total Hip Arthroplasty System (THA) system is used for primary total hip replacement in skeletally mature individuals. The system consists of monolithic cemented and press-fit femoral stems, modular CoCr and BIOLOX® *delta* femoral heads in various sizes and offsets, uncemented acetabular shells and conventional polyethylene liners. Accessory components include distal centralizers, cancellous bone screws and cement restrictors. 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 MALUC™ System is intended for use for cases of severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis or congenital hip dysplasia, avascular necrosis of the femoral head, acute traumatic fracture of the femoral head or neck, failed previous hip surgery (including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty and/or total arthroplasty), and certain cases of ankylosis.

(a)(6) Comparison of Technological Characteristics:

The MALUC™ Total Hip Arthroplasty 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:
Mechanical testing in accordance with the following standards was performed and the subject MALUC™ THA System met all predetermined acceptance criteria: ISO 21535, ASTM F2996, ISO 7206-4, ISO 7206-6, ISO 7206-10, ASTM F2009, ASTM F1820, ASTM F543.

Bacterial endotoxin testing was performed in accordance with USP <85> and ANSI/AAMI ST72 and met the predetermined acceptance criteria.

(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 MALUC™ Total Hip Arthroplasty System demonstrates substantial equivalence to the identified predicate devices.