January 19, 2018

StelKast, Inc.
% Hollace Rhodes
Senior Director, Orthopedic Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisors
1050 K Street NW
Suite 1000
Washington, District of Columbia 20001

Re: K173875
Trade/Device Name: GENFlex2 Total Knee System - Ultra-Congruent CR Tibial Insert
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, OIY
Dated: December 20, 2017
Received: December 21, 2017

Dear Hollace Rhodes:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K173875

Device Name
GENFlex2 Total Knee System – Ultra-Congruent CR Tibial Insert

Indications for Use *(Describe)*

The GENFlex2 Total Knee System is intended for:
• Total knee replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis, and/or post-traumatic degenerative problems.
• Revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.
The 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.

510(k) Summary

Manufacturer: StelKast, Inc.
200 Hidden Valley Road
McMurray, PA 15317
Phone: 724.731.2208
Fax: 727.941.5987

Contact: Mr. David Stumpo
Vice President of Product Development

Prepared By: Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street NW, Suite 1000
Washington, DC 20001
Phone: 202.552.5800

Date Prepared: December 20, 2017

Device Trade Name: GEN*Flex*$_2$ Total Knee System – Ultra-Congruent CR Tibial Insert

Device Common Name: Total Knee Replacement System

Classification: 21 CFR 888.3560
Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Class II

Product Codes: JWH, OIY

Indications for Use: The GEN*Flex*$_2$ Total Knee System is intended for:

- Total knee replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis, and/or post-traumatic degenerative problems.
- Revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

The device is intended for cemented use only.

Device Description:

The purpose of this Special 510(k) is to add the Ultra-Congruent CR Tibial Insert to the GEN*Flex*$_2$ Total Knee System. The Ultra-Congruent CR Tibial Insert is a component within a cemented total knee joint replacement system comprised of modular components with varying sizes available for each component. The articulating geometry of the Ultra-Congruent CR Tibial Insert provides for increased stability relative to the predicate CR insert. The inserts are manufactured from EXp Vitamin E Polyethylene and Conventional Polyethylene.

Predicate Devices:

The GEN*Flex*$_2$ Ultra-Congruent CR Tibial Insert is substantially equivalent to the predicate inserts of the GEN*Flex*$_2$ Total Knee System (K162222), originally cleared as the Proven Total Knee System (K980276, K063211, and K122883) with respect to intended use, materials, design, range of available sizes, method of fixation, and performance characteristics. The information summarized in the Design Control Activities Summary demonstrates that the modified geometry of the Ultra-Congruent CR Tibial Insert meets the pre-determined acceptance criteria for the verification activities.

Substantial Equivalence:

A/P constraint testing was performed on the modified GEN*Flex*$_2$ Ultra-Congruent CR Tibial Inserts and compared to results for the predicate inserts. Contact area analyses were performed on the modified and predicate devices. All results demonstrate that the modified device performs similarly to the predicate device.

Limulus Amebocyte Lysate (LAL) testing was performed on the implants to establish that the device meets pyrogen limit specifications.