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

September 7, 2016

StelKast, Incorporated
% Mr. David Stumpo
Vice President of Product Development
200 Hidden Valley Road
McMurray, Pennsylvania 15317

Re: K162222
Trade/Device Name: GENflex2 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, OIY
Dated: August 5, 2016
Received: August 8, 2016

Dear Mr. Stumpo:

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)*
K162222

Device Name
GENflex2 Total Knee System

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

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
1331 H Street, NW, 12th Floor
Washington, DC 20005
Phone: 202.552.5800
Fax: 202.552.5798

Date Prepared: August 31, 2016

Device Trade Name: GENflex2 Total Knee System

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 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.

Device Description:

The GENflex2 System is a cemented total knee joint replacement system comprised of modular components with varying sizes available for each component. The purpose of this Special 510(k) is to modify the geometries of the Posterior Stabilized and the Cruciate Retaining tibial insert and femoral component. These components are manufactured from EXp Vitamin E Polyethylene, Conventional Polyethylene and Cobalt Chrome Alloy. Each component is available in a range of sizes that complement each other.

Predicate Devices:

The modified GENflex2 Total Knee System is substantially equivalent to the predicate Proven Total Knee System (K980276, K063211, K122883) with respect to intended use, materials, geometry, range of available sizes, methods of fixation, and performance characteristics. The information summarized in the Design Control Activities Summary demonstrates that the modified geometries of the tibial insert femoral component meet the pre-determined acceptance criteria for the verification activities.

Substantial Equivalence:

Static and fatigue A/P shear testing and engineering analyses of contact area were performed on the modified components of the GENflex2 Total Knee System and the predicate Proven Total Knee System. All results demonstrate that the modified device performs similarly to the predicate device.

Limulus Amebocyte Lysate (LAL) testing was performed on the GENflex2 implants to establish that the device meets pyrogen limit specifications.