StelKast, Inc.
% Hollace Rhodes
Senior Director, Orthopedic Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20005

March 8, 2019

Re: K190276
Trade/Device Name: Provident II Hip Stem
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, JDI, LWJ, LZO, OQH, OQI, KWY
Dated: February 7, 2019
Received: February 8, 2019

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Daniel S. Ramsey -S
2019.03.08 16:29:51 -05'00'

For 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)*

K190276

Device Name

Provident II Hip Stem

Indications for Use *(Describe)*

1. Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis , and avascular necrosis.
2. Rheumatoid Arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed total hip arthroplasty.

Cemented and Uncemented Applications

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.

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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
Contact:	Mr. David Stumpo Vice President of Operations
Prepared By:	Musculoskeletal Clinical Regulatory Advisers, LLC 1050 K Street NW, Suite 1000 Washington, DC 20001 Phone: 202.552.5800
Date Prepared:	March 5, 2019
Device Trade Name:	Provident II Hip Stems
Device Common Name:	Hip Prosthesis
Classification:	21 CFR 888.3358: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis – Class II 21 CFR 888.3350: Hip joint metal/polymer semi-constrained cemented prosthesis – Class II 21 CFR 888.3353: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis – Class II 21 CFR 888.3360: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis – Class II 21 CFR 888.3390: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis – Class II
Product Codes:	LPH, JDI, LWJ, LZO, OQH, OQI, KWY

Indications for Use:

1. Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, and avascular necrosis.
2. Rheumatoid Arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
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Cemented and Uncemented Applications

Device Description:

The purpose of this Special 510(k) is to expand the Provident Hip System with a line extension to the existing Provident Hip Stems. The new stems are to be marketed as the Provident II Hip Stems and feature a shortened stem.

Predicate Devices:

The Provident II Hip Stems are substantially equivalent to the predicate stems of the Provident Hip Stem line (K935484, K946371, K001745, K002796, K094035, K122773), 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 stem length of the Provident II Hip Stem meets the pre-determined acceptance criteria for the verification activities.

Substantial Equivalence:

An engineering analysis was performed on both the modified and predicate stems. All results demonstrate that the modified device performs similarly to the predicate device.

Limulus Amebocyte Lysate (LAL) testing has been performed to establish that the device meets pyrogen limit specifications.