December 16, 2019

Keos
% Maris Garner
Senior Consultant
MRC/X, LLC
6075 Poplar Avenue
Memphis, Tennessee 38119

Re: K193174
Trade/Device Name: Keos Lumbar IBFD
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: November 15, 2019
Received: November 18, 2019

Dear Maris Garner:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent Showalter, PhD
Assistant Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*

K193174

Device Name
Keos Lumbar IBFD

Indications for Use *(Describe)*

The Keos Lumbar IBFD is indicated for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD) of the spine. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. DDD may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels.

These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). The Keos Lumbar IBFD is intended to be used with supplemental spinal fixation systems that have been cleared for lumbosacral spine (i.e. posterior pedicle screws and rod systems, anterior plate systems, and anterior screw and rod systems.) The device(s) is intended to be used with autogenous bone graft.

Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage. The Keos Lumbar IBFD can be used in one of two methods:

Transforaminal Lumbar Interbody Fusion (TLIF) Used as a TLIF, a single device is implanted in the appropriate location (L2-S1) to provide support for a transforaminal approached surgery.

Posterior Lumbar Interbody Fusion (PLIF) Used as a PLIF, two devices are implanted in the appropriate locations (L2-S1) to provide support to the spine for a posterior surgery.

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**
*Keos Lumbar IBFD*
November 15, 2019

**Company:** Keos
1824 Colonial Village Lane
Lancaster, PA, 17601 USA

**Establishment Registration:** **3013921069**

**Primary Contact:** Maris Garner
Phone: 601-946-2244
Email: maris.garner@mrc-x.com

**Company Contact:** Scott Peterson
Phone: 239-259-1491
Fax: 239-216-8131
Email: speterson@keosspine.com

**Trade Name:** **Keos Lumbar IBFD**

**Common Name:** Intervertebral Fusion Device

**Classification:** Class II

**Regulation Number:** 21 CFR 888.3080 (Intervertebral body fusion device)

**Panel:** 87- Orthopedic

**Product Code:** MAX

**Predicate Devices:** **Primary Predicate:**

Keos Lumbar Interbody Fusion Device - K160631 and K163386

**Device Description:**
The Keos Lumbar Intervertebral Body Fusion Devices (IBFD) are used to maintain disc space distraction in skeletally mature adults requiring intervertebral body fusion (IBF). They are designed to be used in conjunction with supplemental spinal fixation instrumentation. The series is comprised of cages of various fixed heights and shapes for placement in the spine. There are different cages designed for specific regions of the spine and approaches to the spine. Each cage has a hollow center to allow

placement of graft material inside of the cage. Ridges on the superior and inferior surfaces of the device help to grip the endplates and prevent expulsion.

Keos Lumbar Intervertebral Body Fusion Devices (IBFD) are made from PEEK radiolucent material and Hydroxyapatite (HA) Enhanced PEEK with embedded tantalum x-ray markers as specified in ASTM F2026 and ASTM F560, respectively.

Surgical instruments are required for implantation of the device. The accessories are manufactured from 17-4 Stainless Steel (per ASTM F899-11), 465 Stainless Steel, Silicon, 6061 Aluminum, 300 and 400 Series Stainless Steel.

**Indication for Use:**

The Keos Lumbar IBFD is indicated for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD) of the spine. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. DDD may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels.

These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). The Keos Lumbar IBFD is intended to be used with supplemental spinal fixation systems that have been cleared for lumbosacral spine (i.e. posterior pedicle screws and rod systems, anterior plate systems, and anterior screw and rod systems.) The device(s) is intended to be used with autogenous bone graft.

Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

The Keos Lumbar IBFD can be used in one of two methods:

Transforaminal Lumbar Interbody Fusion (TLIF) Used as a TLIF, a single device is implanted in the appropriate location (L2-S1) to provide support for a transforaminal approached surgery.

Posterior Lumbar Interbody Fusion (PLIF) Used as a PLIF, two devices are implanted in the appropriate locations (L2-S1) to provide support to the spine for a posterior surgery.

**Substantial Equivalence:**

The subject Keos Lumbar IBFD is substantially equivalent to the following:

**Primary Predicate:** Keos - Lumbar Interbody Fusion Device (K160631, S.E. 07/15/2016 and K163386, S.E. 04/10/2017)

The subject Keos Lumbar IBFD is manufactured using PEEK radiolucent material and Hydroxyapatite (HA) Enhanced PEEK with embedded tantalum x-ray markers and is intended to be used as an intervertebral body fusion device in conjunction with the surgical instruments required for implantation, similar to the predicate device.

The subject device also shares similar indications for use, geometry, and construction with the predicate device.

Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

**Performance Testing:**

Confirmatory testing, including impaction, as well as rationales were provided to demonstrate substantial equivalence.

**Conclusion:**

Based upon the information contained in this submission and the similarities of the subject and predicate devices, the subject Keos Lumbar IBFD is substantially equivalent to the predicate device.