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

April 10, 2017

Keos
Mark Schenk
Director of QA/RA
1824 Colonial Village Lane
Lancaster, Pennsylvania 17601

Re: K163386
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: March 15, 2017
Received: March 17, 2017

Dear Mr. Schenk:

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)*
K163386

Device Name
Keos Lumbar IBFD

Indications for Use *(Describe)*
Keos Lumbar IBFD is indicated for spinal fusion procedure at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). 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 1 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 provided 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.

Traditional 510(k) Summary

as required by section 807.92(c).

Submitter:	Keos 1824 Colonial Village Lane Lancaster, PA 17601
Contact Person	Mark F Schenk Director of QA/RA Phone: 610-507-8255 Email: mfschenk@lokconsulting.net
Date Updated	4/7/17

Trade Name	Keos Lumbar IBFD
Common Name	Intervertebral body fusion device
Device Class	Class II
Classification Name and Number	Intervertebral Fusion Device With Bone Graft, Lumbar intervertebral fusion device with bone graft, cervical 21 CFR 888.3080
Classification Panel:	Orthopedic
Product Code	MAX
Reason for 510k	Update Cleaning Instructions
Predicate Devices	K160631, Keos Lumbar IBFD

Device Description	The series of intervertebral body fusion devices are used to maintain disc space distraction in skeletally mature adults requiring intervertebral body fusion. 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. The series of intervertebral body fusion devices are made from the PEEK radiolucent material and HA enhanced PEEK with embedded tantalum x-ray markers as specified in ASTM F2026 and ASTM F560, respectively.

Indications for Use	Keos Lumbar IBFD is indicated for spinal fusion procedure at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). 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 1 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 provided support to the spine for a posterior surgery.

Materials:	The implant is manufactured from ASTM F2026 implant grade PEEK-OPTIMA and PEEK-OPTIMA LT120HA (PEEK-OPTIMA HA Enhanced).

Statement of Technological Comparison	Keos Lumbar IBFD and its predicate devices have the same indications for use, same design, and test results. The purpose of this submission is to document the cleaning validation for the previously cleared devices.

Nonclinical Test Summary	The following tests were performed to demonstrate that the Keos Lumbar IBFD is substantially equivalent to other predicate devices. • Static and Dynamic Compression Test per ASTM F2077 • X-ray Diffraction (XRD), Fourier Transform Infrared Spectroscopy (FTIR), and X-ray photoelectron Spectroscopy (XPS) were used to evaluate the effects of cleaning on the implants. The results of these studies showed that the Keos Lumbar IBFD met the acceptance criteria.
Clinical Test Summary	No clinical tests were performed.

Sterilization Information	
Implants	The Implant will be shipped non-sterile and will be autoclaveable, validation testing of the process was conducted (using the half-cycle method) to a Sterility Assurance Level (SAL) of 10-6 per ISO 17665.
Instruments and Case	The instrument and case will be shipped non-sterile and will be autoclaveable, validation testing of the process was conducted (using the half-cycle method) to a Sterility Assurance Level (SAL) of 10-6 per ISO 17665.

Conclusion	The Keos Lumbar IBFD is substantially equivalent to its predicate devices. This conclusion is based upon the fact the Keos Cage and its predicate devices have the same indications for use, have a same design and technical characteristics, similar test results, and any differences do not raise question of safety and effectiveness.