510(k) Summary

DEC - 9 2013

Date:	26 September 2013
Sponsor:	K7 LLC 54 Moonrise Way Henderson, NV 89074 Phone: 817.219.4441 Facsimile: 817.326.5524
Contact Person:	Michael D. Smith, Manager
Trade Names:	K7 Lumbar Spacers
Device Classification	Class II
Classification Name:	Intervertebral fusion device with bone graft, lumbar
Regulation:	888.3080
Device Product Code:	MAX
Device Description:	The K7 Lumbar Spacers are a collection of radiolucent interbody devices having variously shaped cross-sections. The superior and inferior surfaces are open with parallel serrations to facilitate implant stability. The implants are available in an assortment of height, length, width and anteroposterior angulation combinations to accommodate a variety of anatomic requirements.
Intended Use:	The K7 Lumbar Spacers are indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with supplemental fixation and with autograft to facilitate fusion
Materials:	K7 Lumbar Spacers are manufactured from polyetheretherketone (PEEK) per ASTM F2026 (VESTAKEEP® i4 R, Evonik Polymers Technologies GmbH). Integral marker pins are manufactured from tantalum according to ASTM F560.
Predicate Devices:	Eminent Spine, Eminent Spine Interbody Fusion System (K090064) DePuy AcroMed, Lumbar I/F Cage® (P960025) DePuy Spine, Cougar LS Lateral Cage System (K090899, K110454) Choice Spine LP, ORIA Natura® (K073669) K2M, Aleutian® IBF System (K082698, K101302 and K110843) Stryker Spine, AVS® PEEK Spacers (K073470, K082014, K101051) Icotec, ETurn Spinal Implant (K100305)

Performance Data:

Mechanical testing of the worst case K7 Lumbar Spacer was performed according to ASTM F2077 and included static and dynamic compression. The subsidence properties were evaluated according to ASTM F2267.

The mechanical test results demonstrate that the K7 Lumbar Spacers performance is substantially equivalent to the predicate devices.

Technological Characteristics:

The K7 Lumbar Spacers possess the same technological characteristics as the predicate devices. These include:

- intended use (as described above),
- basic design (hollow column),
- material (PEEK polymer and tantalum), and
- sizes (widths, lengths and heights are within the range(s) offered by the predicate systems).

Therefore the fundamental scientific technology of the K7 Lumbar Spacers is the same as previously cleared devices.

Conclusion:

The K7 Lumbar Spacers possess the same intended use and technological characteristics as the predicate devices. Therefore the K7 Lumbar Spacer system is substantially equivalent for its intended use.

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

December 9, 2013

K7, LLC
% BackRoads Consulting, Incorporated
Karen E. Warden, Ph.D.
8202 Sherman Road
Chesterland, Ohio 44026

Re: K133126
Trade/Device Name: K7 Lumbar Spacers
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: September 26, 2013
Received: September 30, 2013

Dear Dr. Warden:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 7 – Indications for Use Statement

510(k) Number: K133126

Device Name: **K7 Lumbar Spacers**

Indications for Use:

The K7 Lumbar Spacers are indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with supplemental fixation and with autograft to facilitate fusion.

Prescription Use __X__ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices