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

November 16, 2016

Evolution Spine, LLC
% John Siegel
Chief Operating Officer
LeoNine, LLC
819 S. 5th Street, Suite B
Temple, Texas 76504

Re: K160663
Trade/Device Name: Lumbar Interbody Fusion System (ALIF, PLIF, LLIF, TPLIF)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: October 18, 2016
Received: October 19, 2016

Dear Mr. Siegel:

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 yours,

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)*
K160663

Device Name
Lumbar Interbody Fusion System (ALIF, PLIF, LLIF, TPLIF)

Indications for Use *(Describe)*
This system is 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. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

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.

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Lumbar Interbody Fusion System (ALIF, PLIF, LLIF, TPLIF)
Premarket Notification 510(k) Summary

DATE PREPARED

November 10, 2016

MANUFACTURER

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PANEL CODE

Orthopaedics/87

CLASSIFICATION NAME

21 CFR 888.3080 – Intervertebral Fusion Device with Bone Graft, Lumbar

CLASS

Class II

COMMON NAME

Intervertebral Body Fusion Device, Lumbar (MAX)

TRADE NAME

Lumbar Interbody Fusion System (ALIF, PLIF, LLIF, TPLIF)

PREDICATE DEVICES

Primary: Python, manufactured by Eminent Spine (K090064)
Reference: Cottonmouth, manufactured by Eminent Spine (K090064); K7 Lumbar Spacers, manufactured by K7, LLC (K133126); Opal Spacer, manufactured by Synthes (K072791)

DEVICE DESCRIPTION

The Lumbar Interbody Fusion System consists of instruments and VESTAKEEP PEEK (per ASTM F2026) implants which will be offered in four (4) configurations of various sizes to accommodate individual patient anatomy. The configurations are designed pursuant to a specific surgical approach, and consist of the following: 1) Anterior Lumbar Approach (ALIF); 2) Posterior Lumbar Approach (PLIF); 3) Lateral

Lumbar Approach (LLIF) and 4) Transforaminal Posterior Lumbar Approach (TPLIF). The implants are single use and the system is provided non-sterile.

INDICATIONS and INTENDED USE

Intervertebral Body Fusion Device:

This system is 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. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Documentation was provided to demonstrate that the Subject Lumbar Interbody Fusion System is substantially equivalent to the predicate device: Python Interbody Fusion Device (K090064). The Subject device is substantially equivalent to the predicate devices in intended use, indications for use, materials, technological characteristics, and labelling.

PERFORMANCE DATA

Static and dynamic axial compression, static and dynamic compression shear and static and dynamic torsion following ASTM F2077-14. Subsidence was tested following ASTM F2267-04. Expulsion was tested using a widely accepted and validated methodology. The above listed pre-clinical testing on the Subject device indicate that the Lumbar Interbody Fusion System is substantially equivalent to it predicate device(s).

CONCLUSION

The Lumbar Interbody Fusion System and its predicate(s) have the same intended use, to provide mechanical stability in the lumbar disc space to facilitate biologic fusion. The indications for use of the Subject device are identical to those of the predicate device. Minor differences between the Subject and predicate devices do not raise any new questions of safety or efficacy. Bench testing demonstrated that the differences do not adversely impact device mechanical performance. Based on the intended use, indications for use, technological characteristics, materials, and comparison to the predicate devices, the Subject Lumbar Interbody Fusion System has been shown to be substantially equivalent to legally marketed predicate devices.