DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 5, 2016

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

Re: K160324
Trade/Device Name: Cervical Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: April 6, 2016
Received: April 8, 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 Parts 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" (21CFR 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)*
K160324

Device Name
Cervical Interbody Fusion System

Indications for Use *(Describe)*

This system is indicated for intervertebral fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with the autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

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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Cervical Interbody Fusion System
Premarket Notification 510(k) Summary

DATE PREPARED	February 4, 2016
MANUFACTURER	Evolution Spine 4225 Office Parkway Dallas, TX 75204
CONTACT PERSON	Ashton Kouzbari President 214-682-8536 mak@strategicancillaryservices.com
PREPARED BY	John Siegel COO LeoNine, LLC 819 South 5th Street, Suite B Temple, TX 76504 610-457-5324 john@leoninellc.com
PANEL CODE	Orthopaedics/87
CLASSIFICATION NAME	ODP 888.3080 – Intervertebral Fusion Device with Bone Graft, Cervical
CLASS	Class II
COMMON NAME	Intervertebral Body Fusion Device, Cervical (ODP)
TRADE NAME	Cervical Interbody Fusion System
PREDICATE DEVICES	Primary: Copperhead manufactured by Eminent Spine (K090064) Reference: K7C Spacer manufactured by K7 LLC (K123388)

DEVICE DESCRIPTION

The Cervical Interbody Fusion System consists of instruments and VESTAKEEP PEEK (per ASTM F2026) and tantalum (per ASTM F560) implants which are designed for implantation via an anterior cervical approach. The Cervical Interbody Fusion System is comprised of various sizes to accommodate individual patient anatomy. The implants are single use and the system is provided non-sterile.

INDICATIONS and INTENDED USE

This system is indicated for intervertebral fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with the autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Documentation was provided to demonstrate that the Subject Cervical Interbody Fusion System is substantially equivalent to the predicate Copperhead Interbody Fusion Device (K090064). The Subject device is substantially equivalent to the predicate device 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 non-clinical testing on the Subject device indicate that the Cervical Interbody Fusion System is substantially equivalent to a predicate device(s).

CONCLUSION

The Cervical Interbody Fusion System and its predicate(s) have the same intended use, to provide mechanical stability in the cervical 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 Cervical Interbody Fusion System has been shown to be substantially equivalent to legally marketed predicate devices.