JUL 15 2014

5. 510(K) SUMMARY

Submitter's Name:	Expanding Orthopedics, Inc.
Submitter's Address:	17 West Pontotoc Avenue Suite 200 Memphis, TN 38103
Submitter's Telephone:	901-322-0332
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Authorized Contact Person:	Meredith L. May, MS Empirical Testing Corp. – Empirical Consulting 719.337.7579
Date Summary was Prepared:	15-Jul-14
Trade or Proprietary Name:	FLXfit Intervertebral Body Fusion Device
Common or Usual Name:	Intervertebral Fusion Device With Bone Graft, Lumbar
Classification:	Class II per 21 CFR §888.3080
Product Code:	MAX
Classification Panel:	Orthopedic and Rehabilitation Devices Panel
Predicate Devices:	CoAlign Innovation AccuLiF® TL-PEEK Cage and AccuLiF® TL and PL (K112095, K123281, and K123752) Synthes T-PAL Spacer (K100089) Custom Spine Pathway AVID (K090566) Kiscomedica L-Varlock (K080537)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

EOI FLXfit Intervertebral Body Fusion Device is made From Titanium (Ti6Al4V-ELI per ASTM norm F136). This is an articulated-expanded device with height ranges from 8mm through 14mm. The device also expands in height to provide lordosis angle correction of up to 10°.

INDICATIONS FOR USE

The EOI FLXfit Intervertebral body fusion device is indicated for interbody fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have completed six months of non-operative treatment. The EOI FLXfit device is intended to be used

with supplemental spinal fixation system and with autogenous bone graft.The indication for use for the Expanding Orthopedics FLXfit is similar to those of the predicate devices.

TECHNICAL CHARACTERISTICS

The FLXfit components are manufactured from titanium alloy (ASTM F136). The predicate devices are manufactured from the same or similar materials. It is implanted via a Transforaminal approach and supplemented by posterior fixation. The device is made from two titanium segments that are serrated on the superior and inferior surfaces. The titanium segments are attached (linked) with titanium wedge pins that provide the means to form the implant into its final articulated shape. The device also expands in height to provide lordosis angle correction of up to 10°.

PERFORMANCE DATA

The FLXfit has been tested in the following test modes:

- Static Axial Compression (ASTM F2077)
- Static Compression-Shear (ASTM F2077)
- Dynamic Axial Compression (ASTM F2077)
- Dynamic Compression-Shear (ASTM F2077)
- Subsidence (ASTM F2267 and ASTM F2077)
- Usability cadaveric study conducted to evaluate clinical application of the device, including the expansion mechanism, and intra-operative subsidence

The results of this non-clinical testing show that the strength of the FLXfit is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the FLXfit is substantially equivalent to the predicate device.

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

July 15, 2014

Expanding Orthopedics, Incorporated
% Meredith L. May, MS, RAC
Empirical Consulting, LLC
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K133813
Trade/Device Name: FLXfit Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: June 12, 2014
Received: June 13, 2014

Dear Ms. May:

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,

Ronald P. Jean -S for

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 on last page.

510(k) Number *(if known)*
K133813

Device Name
FLXfit Intervertebral body fusion device

Indications for Use *(Describe)*

The EOI FLXfit Intervertebral body fusion device is indicated for interbody fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have completed six months of non-operative treatment. The EOI FLXfit device is intended to be used with supplemental spinal fixation system and with autogenous bone graft.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

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