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

Expanding Orthopedics, Inc.
% Meredith May
Senior Manager
Empirical Technologies Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

September 15, 2017

Re: K171519
Trade/Device Name: FLXfit™
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: June 15, 2017
Received: June 19, 2017

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 (DICE) 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 (DICE) 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 on last page.

510(k) Number *(if known)*
K171519

Device Name
FLXfit™

Indications for Use (Describe)

The EOI FLXfit™ 15 and 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™ 15 and FLXfit™ devices are intended to be used with supplemental spinal fixation system and with autogenous bone graft.

Important: FLXfit™ 15 must be applied in combination with posterior fusion system such as the EOI Spinal System.

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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510(K) SUMMARY

Submitter's Name:	Expanding Orthopedics
Submitter's Address:	3379 Peachtree Road NE (Buckhead), Suite 555, Atlanta, GA 30326
Submitter's Telephone:	901.322.0332
Contact Person:	Meredith L. May, MS Empirical Testing Corp. 719.337.7579
Date Summary was Prepared	15 September 2017
Trade or Proprietary Name:	FLXfit™
Common or Usual Name:	Intervertebral Body Fusion Device
Classification:	Class II per 21 CFR §888.3080
Product Code:	MAX
Classification Panel:	Orthopedic
Predicate Devices	K133813 FLXfit™ by Expanding Orthopedics Inc - Primary
	K080537 L-Varlock by Kiscomedica - Additional

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

EOI FLXfit15 Intervertebral Body Fusion Device is made from titanium (Ti6Al4V-ELI per ASTM F136). This is an articulated-expanded device with height ranges from 8mm through 13mm. The device also expands in height to provide lordosis angle correction of up to 15°.

INDICATIONS FOR USE

The EOI FLXfit™ 15 and 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™ 15 and FLXfit devices are intended to be used with supplemental spinal fixation system and with autogenous bone graft.

Important: FLXfit™ 15 must be applied in combination with posterior fusion system such as the EOI Spinal System.

TECHNOLOGICAL CHARACTERISTICS COMPARISON

The purpose of this submission is to add the FLXfit 15 with additional lengths and lordotic angles to the FLXfit family of interbody devices. FLXfit 15 Lumbar Interbody Fusion Device is a modified FLXfit™ Lumbar Interbody Fusion Device and adds two main features compared to the current FLXfit: an additional device length option of 32mm to the already existing 40mm) and up to 15° of lordosis correction angle as opposed to the 10° of the original FLXfit™. Those features do not involve any change in the device's mechanism, technical characteristics, material or usability. As such, the differences do not adversely affect the safety and efficacy of the device.

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicates:

- Indications for use
- Materials of manufacture
- Structural support mechanism

PERFORMANCE TESTING SUMMARY

In support of this Traditional 510(k) Premarket Notification, Expanding Orthopedics has conducted mechanical testing to demonstrate that the modifications to the FLXfit15 Lumbar Interbody Fusion System provide adequate and substantially equivalent mechanical strength for their intended use. The tests conducted were:

- Dynamic and static compression per ASTM F2077
- Dynamic and static shear compression per ASTM F2077
- Subsidence per ASTM F2267

CONCLUSION

The subject modified is FLXfit15 Lumbar Interbody Fusion System is similar to the previously cleared FLXfit Lumbar Interbody Fusion System. The subject FLXfit15 Lumbar Interbody Fusion System has similar intended uses, indications, technological characteristics, and principles of operation as the predicate device. The modifications raise no new types of safety or effectiveness questions. The overall technology characteristics and mechanical performance data

lead to the conclusion that the FLXfit15 Lumbar Interbody Fusion System is substantially equivalent to the predicate device.