DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 16, 2017

Kalitec Direct, LLC
% Mr. Justin Eggleton
Senior Director, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street Northwest, Suite 1000
Washington, District of Columbia 20001

Re: K163471
Trade/Device Name: Kalitec Direct InSePtion™ MIS Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: February 16, 2017
Received: February 17, 2017

Dear Mr. Eggleton:

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,

Lori A. Wiggins -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 below.

510(k) Number *(if known)*
K163471

Device Name
Kalitec Direct InSePtion™ MIS Fixation System

Indications for Use *(Describe)*
The Kalitec Direct InSePtion™ MIS Fixation System is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1 – S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e. fracture or dislocation), and/or tumor. The Kalitec Direct InSePtion™ MIS Fixation System is not intended for standalone use, and is intended for use with autograft or allograft.

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Device Trade Name: Kalitec Direct InSePtion™ MIS Fixation System

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Date Prepared: March 14, 2017

Classification: 21 CFR §888.3050, Spinal interlaminal fixation orthosis

Class: II

Product Codes: PEK

Primary Predicate Device: NuVasive Affix Spinous Process Plate System (K133052)

Additional Predicates:
Lanx Aspen Spinal Fixation System (K071877)
Kalitec Direct CosmoLock Pedicle Screw System (K140678)

Indications For Use: The Kalitec Direct InSePtion™ MIS Fixation System is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1 – S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e. fracture or dislocation), and/or tumor. The Kalitec Direct InSePtion™ MIS Fixation System

is not intended for standalone use, and is intended for use with autograft or allograft.

Device Description: The Kalitec Direct InSePtion™ MIS Fixation System implant is a posterior non-pedicle supplemental fixation device utilized to achieve supplemental fusion in the non-cervical spine. The system is made of titanium alloy and includes eight color coded sizes, ranging from 8 mm to 18 mm.

Predicate Device: Kalitec Direct InSePtion™ MIS Fixation System was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and materials used. These devices include the Lanx Spinous Process Fusion Plate (K071877) and the NuVasive Affix (K133052).

Performance Testing: Testing performed on this device indicates that the Kalitec Direct InSePtion™ MIS Fixation System is substantially equivalent to predicate devices. ASTM F1717 performance standards were adhered to and all applicable requirements were met. This testing included static compression bending, static torsion, dynamic compression bending, and disassociation testing in UHMWPE test blocks. Finite Element Analysis was also performed to characterize device performance.

Substantial Equivalence: The subject Kalitec Direct InSePtion™ MIS Fixation System is substantially equivalent to the predicate Lanx Aspen Spinal Fixation System (K071877) and NuVasive Affix Spinous Process Plate System (K133052) with respect to indications, design, materials, function, and performance.

Conclusion: The Kalitec Direct InSePtion™ MIS Fixation System is substantially equivalent to predicate devices.

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