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

Paradigm Spine, LLC
% Mr. Justin Eggleton
Senior Director, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, District of Columbia 20005

September 8, 2016

Re: K153302
Trade/Device Name: coflex-IF
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: July 28, 2016
Received: July 29, 2016

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 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)*
K153302

Device Name
coflex-IF

Indications for Use *(Describe)*
The coflex-IF is a posterior, non-pedicle supplemental fixation device intended for use with an interbody cage as an adjunct to fusion at a single level in the lumbar spine (L1 - S1). It is intended for attachment to the spinous processes for the purpose of achieving stabilization to promote fusion in patients with degenerative disc disease - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies - with up to Grade 1 spondylolisthesis.

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

Device Trade Name: coflex-IF

Manufacturer:
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New York, NY 10022
Phone: (212) 583-9700
Fax: (212) 826-9509

Contact:
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Date Prepared: September 6, 2016

Classification: 21 CFR §888.3050, Spinal Interlaminal Fixation Orthosis

Class: II

Product Code: PEK

Primary Predicate: coflex-F system (K112595, K093438)

Additional Predicates: Lanx ASPEN (K071877)
NuVasive Affix (K073278)

Indications For Use:
The coflex-IF is a posterior, non-pedicle supplemental fixation device intended for use with an interbody cage as an adjunct to fusion at a single level in the lumbar spine (L1-S1). It is intended for attachment to the spinous processes for the purpose of achieving stabilization to promote fusion in patients with degenerative disc disease – defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies – with up to Grade 1 spondylolisthesis.

Device Description:
The coflex-IF system is an implant system for interlaminar/interspinous fixation within lumbar interbody fusion surgery. It consists of a single, U-shaped component, fabricated from medical grade titanium alloy (Ti6Al4V). A set of two wings extends vertically from the superior long arm of the device, with a second set of wings extending below the inferior long arm. A screw and sleeve are inserted through a prepared hole and fixes the crimped wings to the superior and inferior spinous processes.

The purpose of this Special 510(k) is to add a notch in the posterior portion of the U-shaped body. The modifications do not affect the intended use of the device or alter the fundamental scientific technology of the device.

Predicate Device(s):
The modified coflex-IF is substantially equivalent to the predicate coflex-F (Paradigm Interspinous Fusion Plate) previously cleared in K112595 and K093438 with respect to indications, design, function, and materials.

Performance Testing

Mechanical testing was performed on coflex-IF, providing sufficient proof for functional safety and performance regarding the mechanical stability and properties. The following three tests were performed (according to ASTM F 1717-13): static compression bending, static torsion, and compression bending fatigue. Results demonstrated equivalent performance to the predicate device.

Substantial Equivalence:
The worst case device was subjected to mechanical testing. The results demonstrate that the acceptance criteria defined in the Design Control Activities Summary were met and the coflex-IF is substantially equivalent to the predicate device(s).

Conclusion:
The coflex-IF is substantially equivalent to previously cleared devices with respect to its indications for use, design, function, materials, and performance.