Paradigm Spine GmbH
% Justin Eggleton
Vice President Spine Regulatory Affairs
MCRA, LLC
1050 K Street NW
Suite 1000
Washington, District of Columbia 20001

August 4, 2020

Re: K201704
Trade/Device Name: CoFix System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal Interlaminal Fixation Orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: June 15, 2020
Received: June 22, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Colin O'Neill, M.B.E.
Acting Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201704

Device Name
CoFix System

Indications for Use *(Describe)*

The CoFix System 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.

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

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510(k) Summary

Device Trade Name: CoFix System

Manufacturer: Paradigm Spine GmbH
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(906) 226-9909
Phone: (800) 557-9909

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Phone: 202.552.5800

Date Prepared: **June 15, 2020**

Classifications: 21 CFR §888.3050, Spinal interlaminal fixation orthosis

Class: Class II

Product Code: PEK

Primary Predicate Device: K153302 – coflex-IF System
The modified coflex-IF System (CoFix System) is substantially equivalent to the predicate coflex-IF System (K153302), with respect to indications, design, function, and materials.

Indications for Use:
The CoFix System 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 CoFix 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 modify the CoFix Sterilization Tray , which is manufactured from stainless steel. The modifications do not affect the intended use of the device or alter the fundamental scientific technology of the device. The CoFix sterilization tray is intended to hold and protect the system's instruments during transport, storage, and steam sterilization.

The actual therapeutic effect is achieved by the CoFix implants.

Performance Testing Summary:
Functional testing was conducted to validate the sterilization tray's critical functions per EN ISO 17664. Adoptions into an existing steam sterilization validation were performed to ensure clean instrumentation and a sterility assurance level (SAL) of 10^{-6} in accordance with the following:

- AAMI TIR12:2010. Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.
- AAMI TIR30:2011/(R2016). A Compendium of Processes, Materials, Test Methods, and acceptance Criteria for Cleaning Reusable Medical Devices.
- ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012. Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- ISO 17664:2017 Sterilization of Medical Devices – Information to be provided by the manufacturer for the processing of Resterilizable Medical Devices.
- ANSI/AAMI ST81:2004/(R2016). Sterilization of Medical Devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices.

Substantial Equivalence:
The subject device was demonstrated to be substantially equivalent to the predicate cited above with respect to indications, design, function, and performance.

Conclusion:
The CoFix System is substantially equivalent to the previously cleared device with respect to its indications for use, design, function, and performance.