MiRus™, LLC
Mr. Jordan Bauman
Director of Regulatory Affairs and Quality
2150 Newmarket Parkway
Marietta, Georgia 30067

June 6, 2019

Re: K190618
Trade/Device Name: RIGEL™ PEEK Anterior Cervical Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: May 31, 2019
Received: June 3, 2019

Dear Mr. Bauman:

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 CAPT Raquel Peat, PhD, MPH, USPHS
Director
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

K190618

Device Name

RIGEL™ PEEK Anterior Cervical Interbody Fusion System

Indications for Use *(Describe)*

The RIGEL™ PEEK Anterior Cervical Interbody Fusion System is an anterior cervical interbody indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level or two contiguous levels from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. Devices are to be used with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation.

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

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92(c).

I. SUBMITTER

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Tel: (678)-324-6272
Fax: (678) 401-5607

II. OFFICIAL CORRESPONDENT

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Fax: (678) 401-5607

III. DATE PREPARED

March 8, 2019

IV. DEVICE

Name of Device	RIGEL™ PEEK Anterior Cervical Interbody Fusion System
Common Name	Intervertebral body fusion device
Classification Name	21 CFR 888.3080
Regulatory Class	Class II
Product Codes	ODP
Submission Type	Traditional 510(k)

V. PREDICATE DEVICE

Cervical Interbody Fusion System - Evolution Spine, LLC - K160324 (primary predicate)
MiRus™ Lumbar Interbody Fusion System - MiRus, LLC - K182920 (additional predicate)

VI. DEVICE DESCRIPTION

The RIGEL™ Interbody Fusion System consist of implants manufactured from medical implant grade VESTAKEEP®i4R PEEK per ASTM F2026-17 with tantalum markers fabricated from medical implant grade ASTM F560-17. The Interbody Fusion Devices are offered in three footprints, various heights, and lordosis to accommodate different patient anatomy and an anterior surgical approach. The implants will be provided non-sterile and are intended for single use only.

VII. INDICATIONS FOR USE

The RIGEL™ PEEK Anterior Cervical Interbody Fusion System is an anterior cervical interbody indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level or two contiguous levels from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. Devices are to be used with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation.

VIII. PREDICATE DEVICE COMPARISON

The documentation provided shows that the RIGEL™ PEEK Anterior Cervical Interbody Fusion System is substantially equivalent to the predicate devices in intended use, indications for use, materials, technological characteristics and labeling.

IX. PERFORMANCE DATA

Static and dynamic compression and static and dynamic shear were performed adhering to ASTM F2077-17. Subsidence testing was performed adhering to ASTM F2267-04. The preclinical testing listed above that was performed on the RIGEL™ PEEK Anterior Cervical Interbody Fusion System indicate that it is substantially equivalent to the predicate devices in mechanical performance.

X. CONCLUSONS

The RIGEL™ PEEK Anterior Cervical Interbody Fusion System does not raise any new questions of safety or efficacy when compared to the predicate device(s). The RIGEL™ PEEK Anterior Cervical Interbody Fusion System has demonstrated that it is substantially equivalent in mechanically performance, indications for used, intended use, technological characteristics, materials and labeling to legally marketed predicate devices.