October 27, 2023

MiRus, LLC
Jordan Bauman
Vice President, Regulatory Affairs
1755 West Oak Parkway, Suite 100
Marietta, Georgia 30062

Re: K232348
Trade/Device Name: RIGEL™ 3DR Standalone Anterior Cervical Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: August 29, 2023
Received: August 29, 2023

Dear Jordan 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Katherine D. Kavlock -S

for
Brent Showalter, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232348

Device Name
RIGEL™ 3DR Standalone Anterior Cervical Interbody Fusion System

Indications for Use *(Describe)*
The RIGEL™ 3DR Standalone Anterior Cervical Interbody Fusion System is a standalone anterior cervical interbody fusion system indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one or two contiguous disc 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.

The RIGEL™ 3DR Standalone Anterior Cervical Interbody Fusion System is intended for use with the bone screw fixation provided and requires no additional 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.

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510(k) Summary - K232348

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

I. SUBMITTER

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II. OFFICIAL CORRESPONDENT

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III. DATE PREPARED

August 29, 2023

IV. DEVICE

Name of Device	RIGEL™ 3DR Standalone Anterior Cervical Interbody Fusion System
Common Name	Intervertebral Fusion Device With Integrated Fixation, Cervical
Classification Name	21 CFR 888.3080
Regulatory Class	Class II
Product Codes	OVE
Submission Type	Traditional 510(k)

V. PREDICATE DEVICE

Predicate Device
F3D Cervical Stand-Alone Interbody Fusion System – CoreLink, LLC (K200087)

Reference Device
ANTARES™ 3DR Standalone Anterior Lumbar Interbody Fusion System – MiRus, LLC (K220115)

VI. DEVICE DESCRIPTION

The RIGEL™ 3DR Standalone Anterior Cervical Interbody Fusion System is an integrated anterior cervical interbody fusion device used to provide structural stability following discectomy.

The RIGEL™ 3DR Standalone Anterior Cervical Interbody Fusion System consists of cages additively manufactured from Titanium-6 Aluminum-4 Vanadium ELI per ASTM F3001, screws and locking cams manufactured from Titanium-6 Aluminum-4 Vanadium ELI per

ASTM F136, and instrumentation manufactured from Stainless Steel per ASTM F899. The RIGEL™ 3DR Standalone Anterior Cervical Interbody Fusion System implants are offered in several configurations of various sizes to accommodate different patient anatomy and surgical approaches.

The interbodies are provided sterile packed and are intended for single use only. The bone screws must be steam sterilized prior to use.

VII. INDICATIONS FOR USE

The RIGEL™ 3DR Standalone Anterior Cervical Interbody Fusion System is a standalone anterior cervical interbody fusion system indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one or two contiguous disc 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.

The RIGEL™ 3DR Standalone Anterior Cervical Interbody Fusion System is intended for use with the bone screw fixation provided and requires no additional fixation.

VIII. PREDICATE DEVICE COMPARISON

The RIGEL™ 3DR Standalone Anterior Cervical Interbody Fusion System has the same technological characteristics as the predicate device including design, intended use, material composition, function, and range of sizes.

IX. PERFORMANCE DATA

The mechanical performance profile of the RIGEL™ 3DR Standalone Anterior Cervical Interbody Fusion System was assessed through static and dynamic construct testing in accordance with the following test methods:

- Static and dynamic compression testing (ASTM F2077-18)
- Static and dynamic compression shear testing (ASTM F2077-18)
- Static and dynamic torsion testing (ASTM F2077-18)
- Subsidence testing (ASTM F2267-04)

X. CONCLUSIONS

The RIGEL™ 3DR Standalone Anterior Cervical Interbody Fusion System has the same intended use, indications for use, labeling, and technological characteristics as the predicate system, including the same design features, geometries, sizes, and materials. Performance data demonstrate that the RIGEL™ 3DR Standalone Anterior Cervical Interbody Fusion System is substantially equivalent to legally marketed predicate systems.