



June 11, 2020

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

Re: K200685

Trade/Device Name: RIGEL™ 3DR 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: March 13, 2020
Received: March 16, 2020

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,

Brent Showalter, Ph.D.
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

Indications for Use

See PRA Statement below.

510(k) Number (if known) Not Known
K200685

Device Name

RIGEL™ 3DR Anterior Cervical Interbody Fusion System

Indications for Use (Describe)

The RIGEL™ 3DR 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.

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K200685 - 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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II. OFFICIAL CORRESPONDENT

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III. DATE PREPARED

March 13, 2020

IV. DEVICE

Name of Device	RIGEL™ 3DR 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

Primary Predicate
RIGEL™ PEEK Anterior Cervical Interbody Fusion System (K190618)
Additional Predicate
EIT Cellular Titanium® Cervical Cage (K170503)

VI. DEVICE DESCRIPTION

The RIGEL™ 3DR (3D-printed Randomized-lattice) Anterior Cervical Interbody Fusion System consist of implants manufactured from Titanium 6AL-4V ELI per ASTM F3001-14 and instrumentation manufactured from stainless steel per ASTM F899. The Interbody Fusion Device is offered in various footprints, heights, and lordosis to accommodate different patient anatomy and the Anterior Cervical Surgical Approach. The implants will be provided sterile and are intended for single use only.

VII. INDICATIONS FOR USE

The RIGEL™ 3DR 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 RIGEL™ 3DR Anterior Cervical Interbody Fusion System has the same intended use, indications for use, labeling, and technological characteristics as the predicate systems, including the same design features, geometries, sizes, and materials.

IX. PERFORMANCE DATA

The mechanical performance profile of the RIGEL™ 3DR Anterior Cervical Interbody Fusion System was assessed through static and fatigue 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)
- Expulsion testing

X. CONCLUSIONS

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