September 11, 2023

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

Re: K232154
Trade/Device Name: MiRus 3DR Lateral Lumbar Interbody Fusion System with Integrated Plate Fixation
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: July 19, 2023
Received: July 20, 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 (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 -S

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)*
K232154

Device Name
MiRus 3DR Lateral Lumbar Interbody Fusion System with Integrated Plate Fixation

Indications for Use *(Describe)*
The MiRus™ 3DR Lumbar Interbody Fusion System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L1-L2 to L5-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Devices are to be used with autogenous or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral body fusion device.

When used with or without the MiRus MoRe Lateral Lumbar Plating System, the system is indicated for use with supplemental fixation cleared by the FDA for use in the lumbar spine.

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

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

September 7, 2023

IV. DEVICE

Name of Device	MiRus 3DR Lateral Lumbar Interbody Fusion System with Integrated Plate Fixation
Common Name	Intervertebral Body Fusion Device
Classification Name	21 CFR 888.3080
Regulatory Class	Class II
Product Codes	OVD, MAX
Submission Type	Traditional 510(k)

V. PREDICATE DEVICE

Primary Predicate
CASCADIA Interbody System – K2M (K172941)
Additional Predicate
MiRus 3D Printed Lumbar Interbody Fusion Systems – MiRus, LLC (K191906)
Reference Device
CYGNUS™ MoRe Anterior Cervical Plate System – MiRus, LLC (K220441)

VI. DEVICE DESCRIPTION

The MiRus 3DR Lateral Lumbar Interbody Fusion System with Integrated Plate Fixation is a spinal intervertebral body fusion device used to provide structural stability following lateral lumbar interbody fusion for lumbar degenerative disorders.

The MiRus 3DR LLIF is additively manufactured from Titanium-6 Aluminum-4 Vanadium ELI per ASTM F3001.

The MiRus MoRe Lateral Lumbar Plating System consists of a lateral plate manufactured from Molybdenum-47.5 Rhenium Alloy (MoRe) per ASTM F3273, bone screws, locking cam mechanism, and a connecting screw manufactured from Titanium-6 Aluminum-4 Vanadium ELI per ASTM F136.

Instrumentation is manufactured from Stainless Steel per ASTM F899. The system is offered in several configurations of various sizes to accommodate different patient anatomy and surgical approaches.

VII. INDICATIONS FOR USE

The MiRus™ 3DR Lumbar Interbody Fusion System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L1-L2 to L5-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Devices are to be used with autogenous or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral body fusion device.

When used with or without the MiRus MoRe Lateral Lumbar Plating System, the system is indicated for use with supplemental fixation cleared by the FDA for use in the lumbar spine.

VIII. PREDICATE DEVICE COMPARISON

The MiRus 3DR Lateral Lumbar Interbody Fusion System with Integrated Plate Fixation 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.

The MiRus™ 3DR LLIF device has been previously cleared (additional predicate - K191906). The MiRus MoRe Lateral Lumbar Plating System device configuration consisting of MoRe alloy plates and titanium alloy locking cams and bone screws is similar to the CYGNUS™ MoRe Anterior Cervical Plate System (reference device - K220441) in terms of materials and design features.

IX. PERFORMANCE DATA

The mechanical performance profile of MiRus 3DR Lateral Lumbar Interbody Fusion System with Integrated Plate Fixation was assessed through dynamic construct testing and screw dissociation testing in accordance with the following test methods:

- Dynamic Compression (ASTM F2077-18)
- Plate/Cage Dissociation Testing

X. CONCLUSIONS

The MiRus 3DR Lateral Lumbar Interbody Fusion System with Integrated Plate Fixation 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 MiRus 3DR Lateral Lumbar Interbody Fusion System with Integrated Plate Fixation is substantially equivalent to legally marketed predicate systems.