May 13, 2022

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

Re: K220115
Trade/Device Name: ANTARES 3DR™ Standalone Anterior Lumbar Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: April 8, 2022
Received: April 11, 2022

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
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)*
K220115

Device Name
ANTARES 3DR™ Standalone Anterior Lumbar Interbody Fusion System

Indications for Use *(Describe)*
The ANTARES 3DR™ Standalone Anterior Lumbar Interbody Fusion System is an interbody fusion device system placed via a variety of open or minimally invasive approaches and indicated for use:

- In skeletally mature patients at one or more levels of the lumbosacral spine (L2-S1)
- In patients having have received 6 months of nonoperative treatment prior to treatment
- With or without screws
- With autograft bone and/or allogenic bone graft comprised of cancellous or corticocancellous bone graft

Standalone Use (with screws)
ANTARES 3DR™ Standalone Anterior Lumbar Interbody Fusion System is intended for stand-alone use in patients with DDD or with degenerative spondylolisthesis at one or two contiguous levels only when used with (1) at least three screws per implant (including at least one screw in each endplate) and (2) when ≤ 20° lordotic implants are used.

Use with Supplemental Fixation (with or without screws)
ANTARES 3DR™ Standalone Anterior Lumbar Interbody Fusion System is intended for use with supplemental fixation in patients with Degenerative disc disease (DDD) defined as back pain with degeneration of the disc confirmed by patient history and radiographic studies, Spinal deformity (degenerative scoliosis or kyphosis), Spondylolisthesis or retrolisthesis, or failed previous fusion (pseudoarthrosis).

When used at more than 2 contiguous levels, with fewer than 3 accompanying screws, or when using implants greater than a 20° lordotic angle, the system must be supplemented by posterior fixation (e.g., pedicle screw system) cleared 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.

510(k) Summary
K220115

1. 510(k) Summary

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

I. SUBMITTER

MiRus™, LLC
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Marietta, Georgia 30062
Tel: (678) 324-6272
Fax: (678) 401-5607

II. OFFICIAL CORRESPONDENT

Jordan Bauman

Vice President, Regulatory Affairs
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Tel: (678) 324-6272
Fax: (678) 401-5607

III. DATE PREPARED

April 08, 2022

IV. DEVICE

Name of Device	ANTARES 3DR™ Standalone Anterior Lumbar Interbody Fusion System
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
HEDRON IA™ Integrated Lumbar Spacers - Globus Medical (K191391)
Additional Predicate Device
MiRus 3D Printed Lumbar Interbody Fusion Systems - MiRus, LLC (K191906)

VI. DEVICE DESCRIPTION

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

The system consists of an interbody cage additively manufactured from Titanium-6 Aluminum-4 Vanadium ELI per ASTM F3001, screws and locking mechanism manufactured

from Titanium-6 Aluminum-4 ELI per ASTM F136, and instrumentation manufactured from Stainless Steel per ASTM F899.

The ANTARES 3DR™ Standalone Anterior Lumbar Interbody Fusion System cages are offered in several configurations of various sizes to accommodate different patient anatomy and surgical approaches.

VII. INDICATIONS FOR USE

The ANTARES 3DR™ Standalone Anterior Lumbar Interbody Fusion System is an interbody fusion device system placed via a variety of open or minimally invasive approaches and indicated for use:

- In skeletally mature patients at one or more levels of the lumbosacral spine (L2-S1)
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When used at more than 2 contiguous levels, with fewer than 3 accompanying screws, or when using implants greater than a 20° lordotic angle, the system must be supplemented by posterior fixation (e.g., pedicle screw system) cleared for use in the lumbar spine.

VIII. PREDICATE DEVICE COMPARISON

The ANTARES 3DR™ Standalone Anterior Lumbar Interbody Fusion System and the predicate device have the same intended use, indications for use, design functions, material composition, range of sizes, and instrumentation. The ANTARES 3DR™ Standalone Anterior Lumbar Interbody Fusion System and the predicate device are additively manufactured from titanium alloy per ASTM F3001. In terms of design features, the predicate system is limited to a 3-screw hole configuration whereas the ANTARES 3DR™ Standalone Anterior Lumbar Interbody Fusion System consists of a 6-screw hole design that allows for the surgeon to choose configurations most suitable for a wide range of patients.

IX. PERFORMANCE DATA

The mechanical performance profile of the ANTARES 3DR™ Standalone Anterior Lumbar 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)
- Subsidence testing (ASTM F2267-04)
- Expulsion testing (ASTM Draft Standard F-04.25.02.02)

X. CONCLUSIONS

The ANTARES 3DR™ Standalone Anterior Lumbar 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 ANTARES 3DR™ Standalone Anterior Lumbar Interbody Fusion System is substantially equivalent to legally marketed predicate systems.