March 13, 2019

MiRus, LLC
Jordan Bauman
Director of Regulatory Affairs and Quality
2150 Newmarket Parkway SE, Suite 108
Marietta, Georgia 30067

Re: K182920
Trade/Device Name: MiRus™ Lumbar Interbody Fusion System consisting of CALLISTO™ PEEK Posterior Lumbar Interbody Fusion (PLIF); HYPERION™ PEEK Transforaminal Lumbar Interbody Fusion (TLIF); CALPYSO™ PEEK Lateral Lumbar Interbody Fusion (LLIF); ANTARES™ PEEK Anterior Lumbar Interbody Fusion (ALIF)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: February 11, 2019
Received: February 12, 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Melissa Hall -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

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 *(if known)*: K182920

Device Name

MiRus™ Lumbar Interbody Fusion System consisting of CALLISTO™ PEEK Posterior Lumbar Interbody Fusion (PLIF); HYPERION™ PEEK Transforaminal Lumbar Interbody Fusion (TLIF); CALPYSO™ PEEK Lateral Lumbar Interbody Fusion (LLIF); ANTARES™ PEEK Anterior Lumbar Interbody Fusion (ALIF)

Indications for Use *(Describe)*

The MiRus™ Lumbar Interbody Fusion System consisting of CALLISTO™ PEEK Posterior Lumbar Interbody Fusion (PLIF); HYPERION™ PEEK Transforaminal Lumbar Interbody Fusion (TLIF); CALPYSO™ PEEK Lateral Lumbar Interbody Fusion (LLIF); ANTARES™ PEEK Anterior Lumbar Interbody Fusion (ALIF) 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 and/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.

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

II. OFFICIAL CORRESPONDENT

Jordan Bauman
Director of Regulatory Affairs and Quality
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2150 Newmarket Parkway SE
Suite 108
Marietta, Georgia 30067
Tel: (678)-324-6272
Fax: (678) 401-5607

III. DATE PREPARED

December 18, 2018

IV. DEVICE

Name of Device	MiRus™ Lumbar Interbody Fusion System consisting of: CALLISTO™ PEEK Posterior Lumbar Interbody Fusion (PLIF); HYPERION™ PEEK Transforaminal Lumbar Interbody Fusion (TLIF); CALPYSO™ PEEK Lateral Lumbar Interbody Fusion (LLIF); ANTARES™ PEEK Anterior Lumbar Interbody Fusion (ALIF)
Common Name	Intervertebral body fusion device
Classification Name	21 CFR 888.3080
Regulatory Class	Class II
Product Codes	MAX
Submission Type	Traditional 510(k)

V. PREDICATE DEVICE

Amendia Interbody Fusion Devices
(K160924- Primary Predicate)
(K151310- Additional Predicate)
(K151322- Additional Predicate)

VI. DEVICE DESCRIPTION

The MiRus™ Lumbar Interbody Fusion System consist of implants manufactured from VESTAKEEP®i4R PEEK per ASTM F2026 and instrumentation manufactured from stainless steel per ASTM F899. The Interbody Fusion Devices are offered in four configurations of

various sizes to accommodate different patient anatomy and the surgical approaches listed; Posterior Lumbar Approach (PLIF), Transforaminal Lumbar Approach (TLIF), Lateral Lumbar Approach (LLIF), and Anterior Lumbar Approach (ALIF). The implants will be provided non-sterile and are intended for single use only.

VII. INDICATIONS FOR USE

The MiRus™ Lumbar Interbody Fusion System consisting of CALLISTO™ PEEK Posterior Lumbar Interbody Fusion (PLIF); HYPERION™ PEEK Transforaminal Lumbar Interbody Fusion (TLIF); CALPYSO™ PEEK Lateral Lumbar Interbody Fusion (LLIF); ANTARES™ PEEK Anterior Lumbar Interbody Fusion (ALIF) 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 and/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.

VIII. PREDICATE DEVICE COMPARISON

The documentation provided shows that the MiRus™ Lumbar Interbody Fusion System consisting of CALLISTO™ PEEK Posterior Lumbar Interbody Fusion (PLIF); HYPERION™ PEEK Transforaminal Lumbar Interbody Fusion (TLIF); CALPYSO™ PEEK Lateral Lumbar Interbody Fusion (LLIF); ANTARES™ PEEK Anterior Lumbar Interbody Fusion (ALIF) 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 Expulsion of the device was evaluated per widely accepted methodology. The preclinical testing listed above that was performed on the MiRus™ Lumbar Interbody Fusion System consisting of CALLISTO™ PEEK Posterior Lumbar Interbody Fusion (PLIF); HYPERION™ PEEK Transforaminal Lumbar Interbody Fusion (TLIF); CALPYSO™ PEEK Lateral Lumbar Interbody Fusion (LLIF); ANTARES™ PEEK Anterior Lumbar Interbody Fusion (ALIF) indicate that it is substantially equivalent to the predicate devices in mechanical performance.

X. CONCLUSONS

The MiRus™ Lumbar Interbody Fusion System consisting of CALLISTO™ PEEK Posterior Lumbar Interbody Fusion (PLIF); HYPERION™ PEEK Transforaminal Lumbar Interbody Fusion (TLIF); CALPYSO™ PEEK Lateral Lumbar Interbody Fusion (LLIF); ANTARES™ PEEK Anterior Lumbar Interbody Fusion (ALIF)does not raise any new questions of safety or efficacy when compared to the predicate device(s). The MiRus™ Lumbar Interbody Fusion System consisting of CALLISTO™ PEEK Posterior Lumbar Interbody Fusion (PLIF); HYPERION™ PEEK Transforaminal Lumbar Interbody Fusion (TLIF); CALPYSO™ PEEK Lateral Lumbar Interbody Fusion (LLIF); ANTARES™ PEEK Anterior Lumbar Interbody Fusion (ALIF) 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.