August 20, 2021

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

Re: K210800
Trade/Device Name: IO™ Expandable Lumbar Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: July 19, 2021
Received: July 21, 2021

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 L. 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)*
K210800

Device Name
IO™ Expandable Lumbar Interbody Fusion System

Indications for Use *(Describe)*
The IO™ Expandable 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 autograft 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# K210800
# 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**

Jordan Bauman

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**III. DATE PREPARED**

July 19, 2021

**IV. DEVICE**

| | |
|---|---|
| **Name of Device** | IO™ Expandable Lumbar Interbody Fusion System |
| **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**

Primary Predicate
SABLE™ Expandable Spacer (K192115)
Reference Device
EUROPA Pedicle Screw System (K180337)

**VI. DEVICE DESCRIPTION**

The IO™ Expandable Lumbar Interbody Fusion System is an expandable lumbar interbody fusion device used to provide structural stability in skeletally mature individuals following discectomy.

The IO™ Expandable Lumbar Interbody Fusion System consist of implants manufactured from titanium alloy (ASTM F136). Expansion mechanism components and the drive screw are manufactured from molybdenum rhenium (MoRe) alloy (ASTM F3273).

The system is offered in various sizes to accommodate different patient anatomy requirements. Implants will be provided sterile and are intended for single use only.

## VII. INDICATIONS FOR USE

The IO™ Expandable 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 autograft 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 IO™ Expandable Lumbar Interbody Fusion System and the predicate device have the same intended use, indications for use, design functions, range of sizes, and instrumentation. The predicate device components are manufactured from titanium alloy, PEEK, and cobalt-chromium alloy. The IO™ Expandable Lumbar Interbody Fusion System components are manufactured from titanium alloy and molybdenum-rhenium alloy, which are the same materials as the reference device.

## IX. PERFORMANCE DATA

The mechanical performance profile of the IO™ Expandable Lumbar 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)
- Subsidence testing (ASTM F2267-04)
- Expulsion testing
- Wear debris particulate characterization (ASTM F1877-16)

## X. CONCLUSIONS

The IO™ Expandable Lumbar Interbody Fusion System is substantially equivalent to legally marketed predicate systems with respect to intended use, technical characteristics, design functions, and performance data.