March 8, 2019

Kuros Biosciences BV
℅ Tess van Dam
Clinical Evaluation Specialist
BAAT Medical Products BV
Floris Hazemeijerstraat 800
7555 RJ Hengelo
The Netherlands

Re: K183092
Trade/Device Name: Kuros TLIF Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: January 28, 2019
Received: January 31, 2019

Dear Tess van Dam:

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,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183092

Device Name
Kuros TLIF Cage

Indications for Use *(Describe)*
The Kuros TLIF Cage is intended for use in intervertebral body fusion of the spine. The Kuros TLIF cage is inserted via a posterior approach and can be used in one level or two contiguous levels of the lumbar spine (L1 to S1). The Kuros TLIF cage is designed for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion, and is to be used with supplemental posterior spinal fixation systems for use in the lumbar spine that are cleared by the FDA.

The Kuros TLIF cage is intended for the treatment of patients with Degenerative Disk Disease (DDD) with up to grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients must be skeletally mature and have had at least six months of non-operative treatment.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

4. Traditional 510(k) Summary

1. Date of preparation: January, 28, 2019

2. Applicant:

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3. Application correspondent:

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4. Device Information

Trade Name:	Kuros TLIF Cage
510(k) Number:	K183092/S001
Classification name:	Intervertebral Fusion Device With Bone Graft, Lumbar
Regulation number:	21 CFR §888.3080
Regulation Description:	Intervertebral body fusion device
Regulatory Class:	II
Product Code:	MAX
Panel:	Orthopedic

5. Indications for Use

The Kuros TLIF Cage is intended for use in intervertebral body fusion of the spine. The Kuros TLIF cage is inserted via a posterior approach and can be used in one level or two contiguous levels of the lumbar spine (L1 to S1). The Kuros TLIF cage is designed for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion, and is to be used with supplemental posterior spinal fixation systems for use in the lumbar spine that are cleared by the FDA.

The Kuros TLIF cage is intended for the treatment of patients with Degenerative Disk Disease (DDD) with up to grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients must be skeletally mature and have had at least six months of non-operative treatment.

6. Description of the Device

The Kuros TLIF Cage is an implant intended for use in interbody fusion surgery and is used to restore intervertebral height and facilitate intervertebral body fusion in the spine. The Kuros TLIF Cage is inserted via a posterior (transforaminal) approach and can be used in one level or two contiguous levels of the lumbar spine (L1 to S1). The Kuros TLIF cage is designed for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and should be used in combination with supplemental posterior spinal fixation systems, intended for use in the lumbar spine and cleared by the FDA.

The Kuros TLIF cage is a rigid spacer, manufactured from PEEK Optima LT1 per ASTM F2026 to maximize biocompatibility, durability, and robustness. The design includes tantalum markers for imaging and has a hollow geometry, allowing the cage to be packed with grafting material per the indications for use. The Kuros TLIF Cages are available in various lengths, heights, and angle variants to accommodate patient anatomy, and are supplied with their specific instrumentation. The device is intended to be used by orthopedic surgeons or neurosurgeons working in a hospital who are trained to use these devices in the patient population specified in the indications for use. The implants are provided sterile to the hospital.

7. Predicate Device(s)

The Kuros TLIF Cage is substantially equivalent to the following devices:

- K153783 Spinevision Spacevision TLIF (primary predicate)
- K130573 Tyber Medical TLIF Cage (additional predicate)
- K182746 Alphatec Spine ATEC ALIF and LLIF Spacer System (additional predicate)
- K170503 EIT Spine TLIF Cage (additional predicate)

8. Summary of Performance Data

The Kuros TLIF Cage conforms to Class II Special Controls Guidance Document: Intervertebral Body Fusion Device- Document issued on: June 12, 2007. Worst case devices were subjected to mechanical testing. Mechanical testing included:

- Static axial compression, dynamic axial compression, static compression shear, dynamic compression shear, performed according to ASTM F2077
- Subsidence testing performed according to ASTM F2267
- Expulsion testing performed according to Endolab protocol

Results demonstrate comparable (or better) mechanical properties to the predicate devices. No clinical data has been presented.

9. Substantial Equivalence Conclusion

The Kuros TLIF Cage is demonstrated to be substantially equivalent to the primary and additional predicates cited above, in terms of intended use, material, design, mechanical properties and function.