September 1, 2021

joimax® GmbH
% Gary Mocnik
Gary Mocnik and Associates
49 Coastal Oak
Aliso Viejo, California 92656

Re: K203014
Trade/Device Name: EndoLIF® Delta-Cage and DoubleWedge-Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: July 28, 2021
Received: August 3, 2021

Dear Gary Mocnik:

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)*
K203014

Device Name
EndoLIF® Delta-Cage and DoubleWedge-Cage

Indications for Use *(Describe)*
The EndoLIF® Delta-Cage and DoubleWedge-Cage are intended 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 L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients may have had previous non-fusion spinal surgery at the involved spinal level(s). EndoLIF® Delta-Cage and DoubleWedge-Cage are to be used with autogeneous bone and implanted via a posterior or posteriolateral approach. The EndoLIF® Delta-Cage and DoubleWedge-Cage are to be used with supplemental FDA cleared fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an EndoLIF® cage.

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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5. 510(k) Summary

I. SUBMITTER

joimax® GmbH
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RaumFabrik 61
76227 Karlsruhe, Germany

Contact person: Gary Mocnik
Phone: (949) 433-0413
Date prepared: June 23, 2020

II. DEVICE
Name of the device: EndoLIF® Delta-Cage and DoubleWedge-Cage
Common or usual name: interbody fusion cage
Classification name: lumbar intervertebral body fusion device
Regulatory Class: 2
Product Code: MAX

III. PREDICATE DEVICE
EndoLIF® On-Cage (K151143)
This predicate has not been subject to a design-related recall

IV. DEVICE DESCRIPTION
The EndoLIF® devices are interbody fusion devices that have a hollow center chamber to permit packing with autogenous bone to facilitate fusion. The superior and inferior surfaces of the device have a rough surface to help prevent movement of the device while fusion takes place. The product family includes cages of a variety of lengths, widths, heights, and lordotic to suit the individual pathology and anatomical conditions of the patient. The device footprint allows for posterior or posterolateral surgical approaches for insertion. All implant components are made from titanium alloy Ti6Al4V ELI using electron beam melting additive manufacturing technology. The EndoLIF® product family is being expanded to include the Delta-Cage and DoubleWedge-Cage implant configurations.

The product family also includes instruments to allow for implant size trialing and insertion.

The EndoLIF® devices are provided in sterile form. All implants are intended for single use only.

V. INDICATIONS FOR USE

The EndoLIF® Delta-Cage and DoubleWedge-Cage are intended 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 L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients may have had previous non-fusion spinal surgery at the involved spinal level(s). EndoLIF® Delta-Cage and DoubleWedge-Cage are to be used with autogeneous bone and implanted via a posterior or posteriolateral approach. The EndoLIF® Delta-Cage and DoubleWedge-Cage are to be used with supplemental FDA cleared fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an EndoLIF® cage.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological characteristics of the EndoLIF® Delta-Cage and DoubleWedge-Cage is highly analogous to the technological characteristics of the EndoLIF® On-Cage previously cleared (K151143) version of the device.

The EndoLIF® Delta-Cage and DoubleWedge-Cage possess the same technological characteristics as one or more of the predicte devices. There include:

- Performance (described below)
- Basic design and materials (additive manufactured structural interbody; titanium alloy)
- Size (dimensions comparable to those marketed by the cleared devices)

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence.

- Static Compression (ASTM F2077)
- Static Compression Shear (ASTM F2077)
- Dynamic Compression (ASTM F2077)
- Static Torsion (ASTM F2077)
- Dynamic Torsion (ASTM F2077)
- Subsidence (ASTM F2267)

The EndoLIF® Delta-Cage and DoubleWedge-Cage met all specified criteria and did not raise new safety or performance questions. Based on the

performance testing the EndoLIF® Delta-Cage and DoubleWedge-Cage were found to have a safety and effectiveness profile that is similar to the predicate device.

VIII. CONCLUSIONS

The design testing performed for the EndoLIF® Delta-Cage and DoubleWedge-Cage demonstrated that the performance of the device is equal to the legally marketed predicate devices.