August 27, 2021

NGMedical GmbH
% Christine Scifert
Partner
MRC Global, LLC
9085 East Mineral Circle, Suite 110
Centennial, Colorado 80112

Re: K211413
Trade/Device Name: BEE® PLIF Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: August 4, 2021
Received: August 5, 2021

Dear Ms. Scifert:

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)*
K211413

Device Name
BEE® PLIF Cage

Indications for Use *(Describe)*
BEE® PLIF cages are indicated for interbody fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. These implants are to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA 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.

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

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510(k) Summary
BEE® PLIF Cage
27 June 2021

Company: NGMedical GmbH
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Official Correspondent: Christine Scifert – MRC Global, LLC
Christine.scifert@askmrcglobal.com
901-831-8053

Trade Name: BEE® PLIF Cage

Common Name: Intervertebral Fusion Device With Bone Graft, Lumbar

Classification: Class II

Regulation Number: 21 CFR 888.3080 (Intervertebral body fusion device)

Panel: Orthopedic

Product Code: MAX

Device Description:
The subject BEE® PLIF Cage is a lumbar interbody fusion device. BEE® PLIF Cage is manufactured from titanium alloy per ASTM F3001 via additive manufacturing. The BEE® PLIF Cage is an intervertebral body fusion device for treatment of lumbar disc degeneration utilizing the posterior lateral approach. BEE®PLIF Cages are offered in several adaptive sizes with varying footprints and lordotic angles to accommodate patient anatomy. The cranial and caudal side of the implant is rough to provide increased stability and to help prevent movement of the device. It is not allowed to use BEE® PLIF implants in contact with components of other manufacturers with the exception of autograft or allograft materials. BEE® PLIF Cage is intended for single use only and is provided sterile, using gamma irradiation.

Indications for Use:
BEE® PLIF cages are indicated for interbody fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants

may be implanted via an open or a minimally invasive posterior approach. These implants are to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

Substantial Equivalence:

The subject device is substantially equivalent to the following predicate devices:

Primary Predicate: Advanced Medical Technologies – FUSE Cages – K100945

Secondary Predicates: EIT Emerging Implant Technologies GmbH – EIT Cellular Titanium® PLIF Cages – K170503, K201605

NG Medical, Ngmh GmbH – BEE®Cage – K200429

The subject and predicate devices are similar in Intended Use, Technological Characteristics, Performance Specifications, and Material. Therefore, it can be concluded that the subject BEE® PLIF Cage does not raise new questions of safety and effectiveness when compared to the predicate devices.

Performance Testing:

In accordance with the FDA Guidance Document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", a biocompatibility evaluation was performed.

The following mechanical testing was performed according to ASTM F2077: Static and dynamic axial compression, Static and dynamic compression shear, and Static and dynamic torsion. Subsidence was performed in accordance with ASTM F2276, in addition to performance of expulsion testing. All tests confirmed that the product met the predetermined acceptance criteria. In particular, non-clinical bench performance testing demonstrated that the BEE®PLIF Cage is substantially equivalent to previously cleared devices.

Conclusion:

Based on the test results and the comparison to the predicate devices, the subject device is determined to be substantially equivalent to the predicate devices.