January 29, 2021

NGMedical GmbH
℅ Christine Scifert
Official Correspondent
MRC Global
9085 East Mineral Circle, Suite 110
Centennial, Colorado 80112

Re: K200429
Trade/Device Name: BEE Cages
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: January 22, 2021
Received: January 25, 2021

Dear Christine 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 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)*
K200429

Device Name
BEE Cage

Indications for Use *(Describe)*
BEE Cages are intended for intervertebral body fusion devices in skeletally mature patients for the treatment of cervical disc degeneration and/or cervical spinal instability as confirmed by imaging studies (radiographs, CT, MRI) that results in radiculopathy, myelopathy and/or pain at one or two contiguous levels from C2-T1. These patients should have had at least six weeks of nonoperative treatment. BEE Cages are to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and in combination with supplemental fixation indicated for cervical fusion procedures.

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: BEE Cervical Cages

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	January 28, 2021
Submitted By	NGMedical GmbH Morschborn 28 66620 Nonnweiler GERMANY +49 (0) 6875 91089-0
Primary Contact	Christine Scifert MRC Global Christine.scifert@askmrcglobal.com 901-831-8053
Trade Name	BEE Cervical Cages
Common Name	Cervical cage
Classification Name	Intervertebral body fusion device - cervical
Class	II
Product Code	ODP
CFR Section	21 CFR section 888.3080
Device Panel	Orthopedic
Primary Predicate Device	EIT Cellular Titanium® Cervical Cage - EIT Emerging Implant Technologies GmbH (K170503)
Reference Predicate Devices	Crystal® - Spinal Elements, Inc. (K073351)
Device Description	The BEE Cervical Cage is an intervertebral body fusion device for treatment of cervical disc degeneration and/or cervical instability utilizing the anterior cervical discectomy and fusion surgical technique. The tapered nose design provides ease of insertion while the convex superior and flat inferior surfaces replicate the patient's vertebral anatomical architecture for maximum surface contact. The cranial and caudal surfaces have a honeycomb geometry that accepts packing of bone graft to help facilitate bony integration. The device consists of implants available in two widths, one depth, seven heights, and three lordotic angles.
Materials	ASTM F136 - Wrought Titanium-6Aluminum-4Vanadium ELI ASTM F3001 - ASTM F3001 Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI ASTM F2924 - ASTM F2924 Additive Manufacturing Titanium-6 Aluminum-4 Vanadium
Intended Use	BEE Cervical Cages were developed as an intercorporal implant for the anterior cervical spondylodesis.

Substantial Equivalence Claimed to Predicate Devices	The BEE Cervical Cages are substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	BEE Cages are intended for intervertebral body fusion devices in skeletally mature patients for the treatment of cervical disc degeneration and/or cervical spinal instability as confirmed by imaging studies (radiographs, CT, MRI) that results in radiculopathy, myelopathy and/or pain at one or two contiguous levels from C2-T1. These patients should have had at least six weeks of nonoperative treatment. BEE Cages are to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and in combination with supplemental fixation indicated for cervical fusion procedures.
Summary of the technological characteristics compared to predicate	Intended Use The BEE Cervical Cages and the predicate devices are all intended to be used to maintain adequate disc space until fusion occurs. Indications for Use All of the devices comply with the indications for use specified in 21 CFR section 888.3080 for cervical interbody fusion devices Material The BEE Cervical Cage uses the same material as the predicate device. Design The BEE Cervical Cage and the predicate are equivalent in terms of shape, material, and manufacturing process. Sizes The BEE Cervical Cage and the predicates are equivalent in their dimensions. Strength The BEE Cervical Cage has greater or equivalent strength values compared to other devices cleared for use in the cervical spine.
Non-clinical Test Summary	The following analyses were conducted: • ASTM F2077 - Test Methods for Intervertebral Body Fusion Devices • ASTM F2267 - Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression The results of these evaluations indicate that the BEE Cervical Cages are equivalent to predicate devices.
Clinical Test Summary	Clinical evidence was provided to demonstrate that the lattice structure did not obstruct the development of fusion.
Conclusions: Non-clinical and Clinical	NGMedical considers the BEE Cervical Cages to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.