January 12, 2024

NGMedical GmbH
℅ Christine Scifert
Partner
MRC Global, LLC
9085 E. Mineral Cir., Suite 110
Centennial, Colorado 80112

Re: K231371
Trade/Device Name: BEE Cervical Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: December 20, 2023
Received: December 20, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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)*

K231371

Device Name
BEE Cervical Cage

Indications for Use *(Describe)*

BEE Cervical Cages are intended for intervertebral body fusion devices in skeletally mature patients for the treatment of cervical disc degeneration and/or cervical instability as confirmed by imaging studies (radiographs, CT, MRI) that results in radiculopathy, myelopathy and/or pain at one or more contiguous levels from C2-T1. These patients should have had at least six weeks of nonoperative treatment. BEE Cervical Cages are to be used with autogenous and/or allogenic 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 – K231371
September 26, 2023

Company: NGMedical GmbH
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Company Contact: Stella Hahn – Head of Regulatory Affairs
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Official Correspondent: Christine Scifert – MRC Global, LLC
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901-831-8053

Trade Name: BEE Cervical Cages

Common Name: Intervertebral Fusion Device With Bone Graft, Cervical

Classification: Class II

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

Panel: Orthopedic

Product Code: ODP

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 various sizes and configurations to be accommodate for varying patient anatomy. The BEE Cervical Cages are fabricated using a Direct Metal Printing (DMP) via additive manufacturing (AM) process using Ti-6Al-4V ELI powder.

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

Substantial Equivalence:
The subject components are substantially equivalent to the following predicate devices:

Primary Predicate:

- BEE Cervical Cages, NGMedical GmbH, K200429

Secondary Predicate:

- uCerv Flux™-C 3D Porous Titanium Cervical Interbody, Ulrich medical USA, Inc, K220696

The subject components indications, technological characteristics and materials are identical to the primary predicate. The secondary predicate has been included to show that the geometry of the expanded sizes of the subject device fall within the size range of the secondary predicate.

Performance Testing:
The following performance testing was conducted for the original clearance of the BEE Cervical Cage System (K200429):

- Compression per ASTM 2077-18
- Compression shear per ASTM 2077-18
- Torsion per ASTM 2077-18
- Subsidence per ASTM 2267-04
- Expulsion per ASTM 2267-04

The following mechanical testing was repeated for the subject device to confirm that the size range expansion does not affect the performance of the system:

- Dynamic compression shear per ASTM 2077-18
- Subsidence per ASTM 2267-04

Results of both tests met the predefined acceptance criteria. The BEE cervical cage range extension is substantially equivalent to the original device.

Conclusion:
Based on the finite element analysis and the comparison to the predicate devices, the subject device is determined to be substantially equivalent to the predicate devices.