November 21, 2025

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

Re: K250560
Trade/Device Name: BEE HA
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: February 18, 2025
Received: February 25, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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)*
K250560

Device Name
BEE HA

Indications for Use *(Describe)*
BEE HA 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 more contiguous levels from C2-T1. These patients should have had at least six weeks of nonoperative treatment. BEE HA 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.

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

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510(k) Summary
BEE HA
October 17, 2025

Company: NGMedical GmbH
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Company Contact: Stella Hahn – Head of Regulatory Affairs
+49 6873 99997-100

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

Trade Name: BEE HA

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 subject BEE HA cage is an anterior cervical interbody fusion device. BEE HA cage is manufactured from PEEK-OPTIMA™ HA Enhanced. The subject device has a hollow chamber to permit packing with bone graft to facilitate fusion. The superior and inferior surfaces of the device have a pattern of teeth to provide increased stability and to help prevent movement of the device. Additionally, the device contains four (4) titanium alloy (Ti6Al4V per ASTM F136) pins to provide imaging visibility for device positioning.

BEE HA cages are offered in several adaptive sizes with varying footprints and lordotic angles to accommodate patient anatomy. The caudal side is flat, the cranial side is domed and the implant is formed conically from anterior to posterior. In the lateral view, the implant has a slightly lordotic form.

BEE HA cage is intended for single use only and is provided sterile, using gamma irradiation.

The purpose of this traditional 510k is to expand the size range offerings for the previously cleared BEE HA.

Indications for Use:

BEE HA 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 more contiguous levels from C2-T1. These patients should have had at least six weeks of nonoperative treatment. BEE HA 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.

Substantial Equivalence:

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

Primary Predicate:

- BEE HA Cage, NGMedical GmbH, K203444

Additional Predicate:

- BEE Cervical Cage, NGMedical GmbH, K231371
- PATRIOT® COLONIAL® Spacer, Globus Medical Inc., K173722

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

Performance Testing:

The following performance testing was conducted for the original clearance of the BEE HA Cage System (K203444):

- Static and Dynamic Compression per ASTM F2077-18
- Static and Dynamic Compression shear per ASTM F2077-18
- Static and Dynamic Torsion per ASTM F2077-18
- Expulsion
- Subsidence per ASTM F2267-04

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

- Dynamic compression shear per ASTM F2077
- Dynamic compression per ASTM F2077
- Dynamic torsion per ASTM F2077

- Subsidence per ASTM F2267

Results of both tests met the predefined acceptance criteria. Therefore, the BEE HA cage range extension is substantially equivalent to the predicate.

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.