March 18, 2021

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

Re: K203444
Trade/Device Name: BEE HA Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: February 15, 2021
Received: February 22, 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,

for
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)*
K203444

Device Name
BEE HA Cage

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary
## BEE HA Cage
## 15 February 2021

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**Company Contact:** Stella Hahn – Head of Regulatory Affairs
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**Official Correspondent:** Christine Scifert – MRC Global, LLC
Christine.scifert@askmrcglobal.com
901-831-8053

**Trade Name:** BEE HA Cage

**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 Hydroxyapetite (HA) Enhanced PEEK-OPTIMA™ HA Enhanced Optima. 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 implants are not to be used with any components from other manufacturers with the exception of use with autogenous and/or allogeneic bone graft.

**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 device is substantially equivalent to the following predicate devices:

Primary Predicate:
Meditech Spine, LLC – Talos®-C (HA) Cervical Intervertebral Body Fusion Devices – K142345

Secondary Predicates:
Globus Medical Inc. – PATRIOT® COLONIAL® Spacer – K173722
Exactech, Inc. (Choice Spine) – Ascendant™ Cervical Spacer System – K150130
NG Medical – BEE Cervical 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 HA 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.

Mechanical testing was performed according to ASTM F2077 and ASTM F2276. All tests confirmed that the product met the predetermined acceptance criteria. In particular, non-clinical bench performance testing demonstrated that the BEE HA Cages 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.