June 6, 2022

Keos
% Maris Garner
Senior Consultant
MRC Global, LLC
9085 East Mineral Circle, Suite 110
Centennial, Colorado 80112

Re: K212450
Trade/Device Name: Keos Anterior Cervical Interbody Fusion Device System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: May 12, 2022
Received: May 13, 2022

Dear Ms. Garner:

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)*

K212450

Device Name

Keos Anterior Cervical Interbody Fusion Devices

Indications for Use *(Describe)*

The Keos Anterior Cervical Interbody Fusion Devices (IBFDs) are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Keos Anterior Cervical IBFD's are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at one disc level (C2-T1) using autogenous bone graft. Keos Anterior Cervical IBFD's are intended to be used with supplemental fixation systems that have been cleared for use in the cervical spine. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

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
Keos Anterior Cervical Interbody Fusion Device System
12 May 2022

Company:
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601-946-2244

Trade Name: Keos Anterior Cervical Interbody Fusion Device System

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 Keos Anterior Cervical Interbody Fusion Device (IBFD) System is composed of anterior cervical spacers and associated instruments. Keos Anterior Cervical IBFD cages are manufactured from polyetheretherketone (PEEK) according to ASTM F2026, as well as Hydroxyapaetite (HA) Enhanced PEEK. 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. Keos Anterior Cervical IBFD cages are offered in several adaptive sizes with varying footprints and lordotic angles to accommodate patient anatomy. Additionally, the device contains six (6) tantalum marker balls per ASTM F560 to provide imaging visibility for device positioning.
The Keos Anterior Cervical Interbody Fusion Device System implants are intended for single use only. All components of the Keos Anterior Cervical IBFD System are provided non-sterile, to be sterilized by the end user.

Indications for Use:

The Keos Anterior Cervical Interbody Fusion Devices (IBFDs) are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Keos Anterior Cervical IBFD's are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at one disc level (C2-T1) using autogenous bone graft. Keos Anterior Cervical IBFD's are intended to be used with supplemental fixation systems that have been cleared for use in the cervical spine. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Substantial Equivalence:

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

Primary Predicate:

BeSpoke Technologies - Tailored-C Cervical IBFD - K200458

Secondary Predicate:

Meditech Spine, LLC - Talos®-C (HA) - K142345

Reference Devices:

Keos – Lumbar Intervertebral Body Fusion Device – K163386, K193174

The subject devices are similar in design to the BeSpoke Technologies Tailored-C Cervical IBFD (K200458) and are designed to be used with the Bespoke Technologies Tailored-C Cervical IBFD instruments. The subject Keos Anterior Cervical IBFDs are manufactured from PEEK-Optima and HA Enhanced PEEK-Optima, similar to the secondary predicate, Talos® C HA (K142345). The materials are identical to those of the Keos Lumbar IBFDs (K163386, K193174).

Performance Testing:

Mechanical testing, including static axial compression, dynamic axial compression, static compression shear, dynamic compression shear, static torsion, dynamic torsion and subsidence, was performed according to ASTM F2077 and ASTM F2267. All tests confirmed that the product met the predetermined acceptance criteria. In particular, non-clinical bench performance testing demonstrated that the Keos Anterior Cervical IBFDs are substantially equivalent to previously cleared devices. Performance testing results are summarized in the **Performance Testing – Bench** section of this Traditional 510(k).

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.