December 14, 2017

Medyssey USA, Inc.
% Christine Scifert
Executive Vice President
MRC-X, LLC
6075 Poplar Ave, Suite 500
Memphis, Tennessee 38119

Re: K170389
Trade/Device Name: TAURUS PEEK Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: November 16, 2017
Received: November 17, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170389

Device Name
TAURUS PEEK Cage System

Indications for Use *(Describe)*

The TAURUS PEEK Cages are indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

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

TAURUS PEEK Cage System

December 11, 2017

Company: Medyssey USA, Inc.
1550 East Higgins Road, Suite 123,
Elk Grove Village, IL 60007
U.S.A.
Tel: 1-847-427-0200
FAX: 1-888-518-9070

Primary Contact: Christine Scifert
Phone: 901-831-8053
christine.scifert@mrc-x.com

Company Contact: Shawn Kim, Director
Director, Medyssey USA
T: 847-427-0200 F: 888-518-9070 Cell: 224-900-9950
shawn@medyssey.com

Trade Name: TAURUS PEEK Cage System

Common Name: Intervertebral fusion device with bone graft, lumbar

Classification: Class II

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

Panel: 87- Orthopedic

Product Code: MAX

Predicate Devices: Primary Predicate:

- Medyssey: BN Cage – K140564

Secondary Predicates:

- Medtronic: CRESCENT® Spinal System – K133216
- Biomet Spine: PEEK-OPTIMA® ALIF Spacer (Enclave Anterior Spinal System) – K081636
- NuVasive: NuVasive® Lumbar Interbody Implants (CoRoent System) – K153782

Device Description:

The TAURUS PEEK Cage System consists of four different models of interbody fusion devices - TAURUS-P™ Cage, TAURUS-AL (ALIF) Cage, and TAURUS-DL Cage. TAURUS PEEK Cage System is intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The devices consist of PEEK cages of various heights, widths, and lengths, which can be inserted across the disc space between two lumbar vertebral bodies to give support and correction during vertebral bod fusion surgeries. All models have serrations on the superior and inferior surfaces of the implants to aid in fixation. All models are designed with hollow regions in the center to house autograft bone graft material. The new bone formation through the implant is intended to provide long-term structural support and biologic fusion at the implanted disc space. Radiopaque tantalum markers have been embedded within the implants to allow for visualization in radiographic images. Associated instruments are available to facilitate the implantation of the devices.

The PEEK material used in the subject interbody cages conforms to ASTM F2026 "Standard Specification for polyetheretherketone (PEEK) Polymers for Surgical Implant Applications" and the tantalum material used conforms to ASTM F560 "Standard Specification for Unalloyed Tantalum for Surgical Implant Applications".

Indications for Use:

The TAURUS PEEK Cage System is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

Substantial Equivalence:

The subject TAURUS PEEK Cage System components were demonstrated to be substantially equivalent with respect to indications for use, design, dimension, and materials to the following interbody devices, previously cleared by the FDA:

Primary Predicate:

- Medyssey: BN Cage – K140564

Secondary Predicates:

- Medtronic: CRESCENT® Spinal System – K133216
- Biomet Spine: PEEK-OPTIMA® ALIF Spacer (Enclave Anterior Spinal System) – K081636
- NuVasive: NuVasive® Lumbar Interbody Implants (CoRoent System) – K153782

Summary of Technological Characteristics:
The subject systems components are similar in sizes, materials and geometry to the predicate components. The subject components have the same indications as the predicate components. The differences in the subject and predicate devices do not render the system not substantially equivalent.

Performance Testing:
Mechanical testing, including, static axial compression bending, static shear compression bending, static torsion, dynamic axial compression fatigue, and subsidence have been performed per ASTM F2077 and ASTM F2267 on the subject TAURUS PEEK Cage devices and the results have shown them to be substantially equivalent to the predicate interbody devices.

Conclusion:
The subject devices are similar to the predicate devices with respect to indications for use, design, dimensions, and materials. The testing performed supports that the subject TAURUS PEEK Cages are substantially equivalent to the predicate devices.