



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 13, 2016

Ouroboros Medical, Inc.
Mr. John To
Chief Technical Officer, Regulatory Affairs
47757 Fremont Boulevard
Fremont, California 94538

Re: K160076

Trade/Device Name: XCage™ Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: September 6, 2016
Received: September 7, 2016

Dear Mr. To:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K160076

Device Name

XCage™ Interbody Fusion System

Indications for Use (Describe)

The XCage™ Interbody Fusion System is indicated for spinal intervertebral body fusion with autogenous bone graft in skeletally mature individuals with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1, following discectomy. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have at least six (6) months of non-operative treatment. Additionally, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). XCage™ System Spacers are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.

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

XCage™ Interbody Fusion System

Traditional 510(k)

Company: Ouroboros Medical, Inc.
47757 Fremont Blvd.
Fremont, CA 94538

**FDA Establishment
Registration Number:** 3010033846

**Correspondent Contact
Information:** John To
CTO, Regulatory Affairs
Tel: (510) 676-0450
Email: jto@ouromed.com

Date Prepared: September 2, 2016

Device Common Name: Intervertebral Body Fusion Device

Device Name: XCage™ Interbody Fusion System

Device Classification: Class II per 21 CFR 888.3080

Classification Name: Intervertebral Fusion Device with Bone Graft, Lumbar

Product Code: MAX

**Predicate Device
Information:** Primary: Ouroboros XCage Interbody Fusion System (K133514)
Additional: Globus Medical, Inc. Caliber® (K102293)

Purpose of Submission:

To achieve premarket clearance for the addition of the XCage Interbody spacer line.

Description of Device and Comparison:

The Ouroboros XCage™ Interbody Fusion System is an expandable lumbar intervertebral body fusion device intended for use in the lumbosacral spine from L2 to S1 and is intended for intervertebral lumbar fusion. The XCage™ Spacer consists of a Shell and a Shim component that are offered in a range of sizes to accommodate variation in patient anatomy. The Shell component is a rectangular frame with struts on all four sides that allow for insertion into the intervertebral body space in a non-expanded form, and subsequent expansion following the insertion of the Shim component. The Shim component has a tapered front end that inserts into and expands the Shell

component to the desired vertical and horizontal dimensions. When fully inserted, the Shim locks within the Shell to provide structural stability for interbody fusion. An integrated “Core” in the Shell serves to anchor the delivery instrument during Shim insertion. Protrusions on the superior and inferior surfaces of the Spacer grip the adjacent vertebral endplates to resist expulsion. The XCage™ Spacer is to be filled with autogenous bone graft material. Once implanted, the XCage™ Spacer is designed to restore intervertebral disc height, provide anterior column support and maintain structural stability of the motion segment to facilitate intervertebral body fusion.

The XCage Interbody Fusion System includes:

1. The spacer components: shell and shim
2. A set of re-useable manual surgical instruments for delivery of the device
3. 23 mm and 27 mm implant lengths
4. 0 and 6 degrees lordotic angles on the implant

The XCage™ shell is made from polyetheretherketone (PEEK) per ASTM F2026, and integrated tantalum radiographic markers per ASTM F560. The XCage™ Shim and Core are made from Titanium alloy per ASTM F136.

The re-usable surgical instruments are made from stainless steel.

Indications for Use:

The XCage™ Interbody Fusion System is indicated for spinal intervertebral body fusion with autogenous bone graft in skeletally mature individuals with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1, following discectomy. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have at least six (6) months of non-operative treatment. Additionally, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). XCage™ System Spacers are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.

Comparison to Predicate Device

The equivalence of XCage™ Interbody Fusion System to the predicates is supported by similarity in intended use, indications for use, technical characteristics, materials and performance.

Performance Data

Mechanical testing was conducted in accordance with *Guidance for Industry and FDA Staff, Class II Special Controls Guidance Document: Intervertebral Fusion Device, June 12, 2007*. The following tests were performed to support the substantial equivalence of the XCage™ Interbody Fusion System to its predicates:

- Static and dynamic axial compression (ASTM F2077)
- Static and dynamic compression shear (ASTM F2077)
- Subsidence (ASTM F2267)

Proposed Labeling:

Draft labeling for the subject Ouroboros XCage™ Interbody Fusion spacer is provided in §14.0. The Indication for Use, Insert, and packaging labels are similar to those included for the predicate XCage Interbody Fusion System (K133514).

Conclusion:

The Ouroboros XCage™ Interbody Fusion System is similar to its predicate devices with respect to intended use, indications for use, technical characteristics, materials and performance. The information presented within this premarket notification application demonstrates that it is substantially equivalent to the predicate Ouroboros XCage Interbody Fusion Spacer (K133514) the Globus Medical Caliber® Spacer (K102293).