MAY 0 1 2014

510(k) Summary

Ouroboros MEDICAL

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) 933-3441 Fax: (866) 931-5422 Email: jto@ouromed.com
Date Prepared:	November 14, 2013
Device Common Name:	Intervertebral Body Fusion Device
Device Classification:	Class II per 21 CFR 888.3080
Classification Name:	Intervertebral Fusion Device with Bone Graft, Lumbar
Product Code:	MAX
Purpose of Submission:	To achieve premarket clearance for the XCage™ Interbody Fusion System
Predicate Device Information:	The XCage™ Interbody Fusion System is substantially equivalent to the Globus Medical, Inc. Caliber® (K102293), Globus Medical, Inc. Patriot® (K072970) and Spine Wave, Inc. StaXx® IB (K123461). All are Class II intervertebral body fusion devices per 21 CFR § 888.3080 and Classification Code MAX.

Description of Device:

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

The Ouroboros XCage™ Interbody Fusion System includes a set of re-useable manual surgical instruments for delivery of the device.

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)

In addition, Simulated Use testing of the XCage™ Interbody Fusion System was performed using both bench and cadaveric models.

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 Globus Medical Caliber® Spacer (K102293), the Globus Medical Patriot® Spacer (K072970) and Spine Wave, Inc. StaXx® IB (K123461), all commercially available interbody fusion devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 1, 2014

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

Re: K133514
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: April 3, 2014
Received: April 4, 2014

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" (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.

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 yours,

Ronald P. Jean -S for

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)*
K133514

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

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