510(k) Summary

JUL 2 9 2014

ADMINISTRATIVE INFORMATION

Manufacturer Name: X-spine Systems, Inc.
452 Alexandersville Rd.
Miamisburg, OH 45342

Telephone (937) 847-8400
FAX (937) 847-8410

Official Contact: David Kirschman, M.D.
Chief Medical Officer

Date Prepared: July 29, 2014

DEVICE NAME

Trade/Proprietary Name:	Irix-A™ Lumbar Integrated Fusion System
Classification Name:	Intervertebral Fusion Device with Integrated Fixation, Lumbar
Regulation Description:	Intervertebral body fusion device
Device Class:	Class II
Product Code:	OVD
Regulation Number:	§888.3080

ESTABLISHMENT REGISTRATION NUMBER

The X-spine Systems, Inc. establishment registration number is 3005031160. The owner/operator number for X-spine Systems, Inc. is 9063903.

INDICATIONS FOR USE

The Irix-A Lumbar Integrated Fusion System is a stand-alone intervertebral body fusion device intended for use in patients with degenerative disc disease (DDD) at one (1) or two (2) contiguous levels of the lumbosacral spine (L2-S1 inclusive). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have had a previous non-fusion spinal surgery at the involved level(s) and may have had up to a Grade I spondylolisthesis or retrolisthesis at the involved level(s). The Irix-A System is intended to be used with autogenous bone graft material, and is to be used with three titanium alloy screws included as part of the system.

DEVICE DESCRIPTION

The Irix-A Lumbar Integrated Fusion System is a stand-alone intervertebral fusion device to restore biomechanical height and act as an aid in fusion of the lumbar spine in anterior discectomy procedures. The device is generally box-shaped with teeth on the superior and inferior faces of the device. The Irix-A implant is manufactured from both titanium alloy (Ti6Al4V) in accordance with ASTM F136 and Invibio PEEK-Optima LT1 in accordance with ASTM F2026, or from Ti6Al4V titanium alloy alone. The device will be supplied with the option of having the superior and inferior surfaces of the device plasma coated with

medical-grade commercially pure titanium (CP Ti) per ASTM F1580. The device is secured in location through the use of bone screws, also manufactured from titanium alloy (Ti6Al4V) per ASTM F136. The devices are provided in various sizes and screws are offered in multiple lengths to adjust for variations in patient anatomy.

The CP-Ti coated devices will be sterile packed with the balance of system components being provided clean and non-sterile. The non-sterile components are to be sterilized by a healthcare professional using a steam autoclave in accordance with the instructions for use provided by X-spine Systems Inc., as well as the instructions provided by the manufacturer of the autoclave.

PREDICATE DEVICES

- Surgicraft Limited – STALIF-TT Intervertebral Body Fusion System (K073109)
- Globus Medical, Inc. – INDEPENDENCE Spacer (K082252)
- Spinal Elements, Inc. – LUCENT OR LUCENT MAGNUM (K110632)

EQUIVALENCE TO MARKETED PRODUCT

X-spine Systems, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the Irix-A Lumbar Integrated Fusion System is substantially equivalent to predicate devices based on a comparison including the following characteristics:

- FDA Product Code
- Indications for Use
- Surgical Approach
- Anatomical Region
- Implant Materials
- Product Dimensions
- Mechanical Performance

PERFORMANCE DATA

The implant components were tested using the following standards:

ASTM F2077 – *Test Methods for Intervertebral Body Fusion Devices*

- Static and dynamic compression
- Static and dynamic compression-shear

ASTM F2267 – *Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device under Static Axial Compression*

In addition to the above standard testing, expulsion testing was performed as part of this submission. There is no cited standard for this test.

For validation of the plasma coating, a full material performance qualification and characterization was performed per published FDA guidance, as well as wear debris particulate analysis from dynamic compression-shear testing.

In summary, the mechanical testing results indicate that the Irix-A Lumbar Integrated Fusion System is substantially equivalent to predicate device performance and is capable of performing in accordance with its intended use.

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

July 29, 2014

X-spine Systems, Incorporated
David Kirschman, M.D.
Chief Medical Officer
452 Alexandersville Road
Miamisburg, Ohio 45342

Re: K133947
Trade/Device Name: Irix-A™ Lumbar Integrated Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: July 3, 2014
Received: July 3, 2014

Dear Dr. Kirschman:

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)*
K133947

Device Name
Irix-A™ Lumbar Integrated Fusion System

Indications for Use *(Describe)*
The Irix-A Lumbar Integrated Fusion System is a stand-alone intervertebral body fusion device intended for use in patients with degenerative disc disease (DDD) at one (1) or two (2) contiguous levels of the lumbosacral spine (L2-S1 inclusive). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have had a previous non-fusion spinal surgery at the involved level(s) and may have had up to a Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The Irix-A System is intended to be used with autogenous bone graft material, and is to be used with three titanium alloy bone screws included as part of the system.

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)*

Katherine D. Kavlock, PhD

Division of Orthopedic Devices

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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PRAStaff@fda.hhs.gov

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