DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 7, 2016

X-Spine Systems, Inc.
Kriss Anderson
Director, Regulatory Affairs
452 Alexandersville Rd.
Miamisburg, Ohio 45342

Re: K162944
Trade/Device Name: Irix-C Cervical Integrated Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: October 20, 2016
Received: October 24, 2016

Dear Kriss Anderson:

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,

Lori A. Wiggins -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)*
K162944

K162944

Device Name

Irix-C Cervical Integrated Fusion System

Indications for Use *(Describe)*

The Irix-C Cervical Integrated Fusion System is a stand-alone cervical intervertebral fusion device intended for spinal fusion procedures at one level (C2 – T1 inclusive) in skeletally mature patients for treatment of degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).

Implants are to be implanted via an open, anterior approach and packed with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

Patients should receive at least six (6) weeks of non-operative treatment prior to treatment with a cervical intervertebral fusion device.

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.

510(K) SUMMARY (21 CFR 807.92)

Irix-C Cervical Integrated Fusion System
November 2, 2016

I. SUBMITTER/MANUFACTURER:

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

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

Establishment Registration Number: 3005031160

Official Contact:

Mr. Kriss Anderson
Director, Regulatory Affairs
Email: kanderson@X-spine.com
Telephone (937) 847-8400, ext. 2137

II. OWNER/OPERATOR:

Xtant Medical Inc.
604 Cruiser Lane
Belgrade, MT 59714

Owner/Operator Number: 10028385

Official Correspondent:

Stephen Smith, Vice President
Regulatory Assurance/ Quality Assurance
Xtant Medical, Inc.
Telephone (406) 388-0480

III. DEVICE

Trade/Proprietary Name:	Irix-C Cervical Integrated Fusion System
Device Common Name:	Intervertebral Body Fusion Device
Regulation Number:	21 CFR §888.3080
Product Code:	OVE -- Intervertebral body fusion device
Regulatory Class:	Class II
Review Panel:	Orthopedic

IV. PREDICATE DEVICES

- Primary: X-spine, Inc.: Irix-C Cervical Integrated Fusion System (K131951)
  - This predicate has not been subject to a design related recall.
- Additional: Orthofix, Inc.: Cervical Stand Alone System (K161280)
  - This predicate has not been subject to a design related recall.

V. REFERENCE DEVICES

The following devices have been 510k cleared with these same or similar technological elements: Indications for Use including autograft and/or allograft, anatomical region of one level (C2—T1 inclusive), OVE product code, and implant materials of PEEK and/or Titanium Alloy:

- Globus Medical: COALITION Spacer (K151939)
- Spinal Elements: Vertu/Vertu TI Bond (K153352)
- Pioneer Surgical Unison (RTI Surgical) (K152793)
- Choice Spine: TomCat (K152515)
- LDR Spine: ROI-C (K151934)
- Centinel Spine: STALIF C/STALIF C-Ti (K150053)

VI. INDICATIONS FOR USE

The Irix-C Cervical Integrated Fusion System is a stand-alone cervical intervertebral fusion device intended for spinal fusion procedures at one level (C2 – T1 inclusive) in skeletally mature patients for treatment of degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).

Implants are to be implanted via an open, anterior approach and packed with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

Patients should receive at least six (6) weeks of non-operative treatment prior to treatment with a cervical intervertebral fusion device.

VII. DEVICE DESCRIPTION

The Irix-C Cervical Integrated Fusion System is a stand-alone intervertebral fusion device designed to restore biomechanical height and act as an aid in fusion of the cervical spine in anterior discectomy procedures. The device is generally boxed shaped with teeth on the superior and inferior faces of the device. The Irix-C implant will be manufactured in either a composite construction of 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 intervertebral fusion device is intended to be used with autograft_and/or allograft comprised of cancellous and/or corticocancellous bone graft. The device is then secured in location through the use of bone screws, also manufactured from titanium alloy (Ti6Al4V) per ASTM F136.

The devices are available in various sizes, and screws are offered in multiple lengths to adjust for variations in patient anatomy. The single-use implants are provided clean and non-sterile. These devices are intended 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.

A series of manual surgical instruments, provided clean and non-sterile, intended to assist with the insertion and placement of the implants, is included in an instrument tray, which is used for instrument sterilization and storage.

The system does not contain software/firmware.

VIII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The technological principle for both the subject and primary predicate device is anterior fixation at one level in the cervical spine for skeletally mature patients with degenerative disc disease.

The subject device, Irix-C Cervical Integrated Fusion System, and the primary predicate device, Irix-C Cervical Integrated Fusion System (K131951) are based on the following technological elements:

- Same FDA Product Code: OVE -- Intervertebral Body Fusion Device.
- Same implant materials: PEEK/Titanium Alloy or All Titanium Alloy.
- Equivalent Indications for Use
- Identical multiple lengths, widths, and heights to account for variations in patient anatomy.
- Equivalent anatomical region.
- Same surgical approach.
- No change to device specifications; therefore mechanical tests were not repeated.

The purpose of this 510(k) submission is to expand the *Indications for Use* to allow the Irix-C Interbody device to be used with allograft comprised of cancellous and/or corticocancellous bone graft, and to update the fusion level.

The predicate Irix-C System is already cleared to be used with autogenous bone graft [autograft], and the predicate Irix-C System is intended to be used for procedures at one level (C3-T1 inclusive). The proposed indication for the Irix-C System is to include the use of allograft for procedures at one level (C2-T1 inclusive). With the exception of the proposed expanded indication adding the inclusion of allograft, and the slight change in vertebrae level, there has been no change to the subject device.

The additional predicate device, Orthofix Cervical Stand Alone System (K161280), is equivalent to the subject device in the following technological elements:

- Same FDA Product Code: OVE -- Intervertebral Body Fusion Device.
- Equivalent implant materials: PEEK/Titanium Alloy.
- Equivalent Indications for Use – only difference is the added indication of allograft comprised of cancellous and/or corticocancellous bone graft and the anatomical region: C2-T1 inclusive instead of C3-T1 inclusive.
- Equivalent multiple lengths, widths, and heights to account for variations in patient anatomy.
- Same surgical approach.

Reference Devices:

In addition to the additional predicate device, Orthofix, numerous other 510k cleared devices have the same or similar technological elements:

- Same FDA Product Code: OVE -- Intervertebral Body Fusion Device.
- Same implant materials: PEEK and/or Titanium Alloy.
- Same Indications for Use –Autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft
- Same anatomical region: C2 -- T1 inclusive

For the years 2016 and 2015, there are at least six 510(k) summaries that include those same or similar technological elements stated above:

- Globus Medical: COALITION Spacer (K151939)
- Spinal Elements: Vertu/Vertu TI Bond (K153352)
- Pioneer Surgical Unison (RTI Surgical) (K152793)
- Choice Spine: TomCat (K152515)
- LDR Spine: ROI-C (K151934)
- Centinel Spine: STALIF C/STALIF C-Ti (K150053)

Therefore, the expansion of the Irix-C Indication for Use to include allograft at one level from C2 to T1 inclusive is not unique, and substantial equivalency of the use of both autograft and allograft at one level (C2 to T1 inclusive) is demonstrated.

IX. PERFORMANCE DATA

No substantial technological changes were made to the existing Irix-C System, nor were any new components added to the Irix-C System. The only change is the expanded Indications for Use. Therefore, no additional testing was required or performed.

X. CONCLUSION

The subject device Irix-C Cervical Integrated Fusion System has been modified to expand the indications to use, and the 510k demonstrates substantial equivalence to legally marketed predicate devices.