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 17, 2016

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

Re: K160959
Trade/Device Name: Xsert™ Lumbar Expandable Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: September 19, 2016
Received: September 21, 2016

Dear Mr. 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 yours,

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)*

K160959

Device Name
Xsert™ Lumbar Expandable Interbody System

Indications for Use *(Describe)*

The Xsert™ Lumbar Expandable Interbody System is intended for spinal fusion procedures at one or two contiguous levels (L2 – S1 inclusive) in skeletally mature patients with degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the lumbosacral spine. DDD patients may also have up to a Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved level(s). These implants are to be packed with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and implanted via a posterior, and/or transforaminal approach. Patients should receive at least six (6) months of non-operative treatment prior to treatment with a lumbosacral intervertebral fusion device.

This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

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 (21 CFR 807.92)

Xsert™ Lumbar Expandable Interbody System
March 31, 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: Xsert™ Lumbar Expandable Interbody System

Device Common Name: Intervertebral Body Fusion Device
Regulation Number: 21 CFR §888.3080
Product Code: MAX (888.3080)
Intervertebral body fusion device

Review Panel: Orthopedic

IV. PREDICATE DEVICES

- Primary: Globus Medical Caliber Spacers (K102293)
  - This predicate has not been subject to a design related recall.
- Additional: X-spine Calix Lumbar Spinal Implant System (K131350)
  - This predicate has not been subject to a design related recall.
- Additional: Stryker AccuLIF® TL and PL Cage (K152651)
  - This predicate has not been subject to a design related recall.
- Additional: Interventional Spine Opticage Interbody Fusion Device (K113527)
  - This predicate has not been subject to a design related recall.

V. REFERENCE DEVICE

X-spine Pedicle Screw System (K152132) – grit blasting technology

- This predicate has not been subject to a design related recall.

VI. INDICATIONS FOR USE

The Xsert™ Lumbar Expandable Interbody System is intended for spinal fusion procedures at one or two contiguous levels (L2 – S1 inclusive) in skeletally mature patients with degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the lumbosacral spine. DDD patients may also have up to a Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved level(s). These implants are to be packed with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and implanted via a posterior, and/or transforaminal approach. Patients should receive at least six (6) months of non-operative treatment prior to treatment with a lumbosacral intervertebral fusion device.

This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

VII. DEVICE DESCRIPTION

The Xsert™ Lumbar Expandable Interbody System of X-spine Systems, Inc. is an expandable interbody system used to provide structural stability in skeletally mature individuals following discectomy. The Xsert™ Lumbar Expandable Interbody System will consist of spacers offered in various shapes and sizes, and their heights can be intra-operatively expanded to fit the anatomical needs of a wide variety of patients. These spacers are intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft material and have features on the superior and inferior surfaces of each device to grip the endplates of the adjacent vertebrae to resist expulsion.

The implant components of the system are manufactured from medical grade Titanium alloy (Ti6AI4V) that complies with ASTM F-136. All implants will be provided clean and sterile, are intended for single use only, and should not be reused under any circumstances.

A series of manual surgical instruments 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.

VIII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The technological principle for both the subject and predicate devices is posterior, fixation at one or two contiguous levels (L2 – S1 inclusive) for skeletally mature patients with degenerative disc disease of the lumbosacral spine.

At a high level, the subject device, and one or more of the predicate devices identified above are based on the following same or equivalent technological elements:

- FDA Product Code: MAX -- Intervertebral Body Fusion Device
- Indications for Use.
- Implants use the same material: Titanium alloy
- Multiple sizes to account for variations in patient anatomy.
- Anatomical region.
- Surgical approach.
- Mechanical performance.
- Sterility of package – Sterile, single use implants

IX. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Mechanical Testing

Mechanical testing was performed as follows:

- Static and Dynamic Compression and Compression Shear per ASTM F2077 *Test Methods for Intervertebral Body Fusion Devices*
- Subsidence per ASTM F2267 *Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression.*
- Expulsion per FDA Guidance – Class II Special Controls Guidance Document: Intervertebral Body Fusion Device

Simulated Use

Design validation of the Xsert™ Lumbar System components and Surgical Technique Guide was performed with surgeons in a cadaveric laboratory evaluation. The surgeons also performed supplementary evaluations of packing the expandable implants with bone graft.

X. CONCLUSION

Based on a review of the information provided, X-spine finds that the Xsert™ Lumbar Expandable Interbody System is substantially equivalent to the referenced predicate device systems. The Xsert™ Lumbar Expandable Interbody System was found to have an equivalent safety and effectiveness profile compared to the referenced predicate systems.