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

August 28, 2017

X-Spine Systems, Inc.
Charlene Brumbaugh
Regulatory Affairs Manager
452 Alexanderville Rd.
Miamisburg, Ohio 45342

Re: K171567
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: May 26, 2017
Received: May 30, 2017

Dear Ms. Brumbaugh:

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,

Katherine D. Kavlock -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)*
K171567

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 I spondylolisthesis or retrolisthesis at the involved level(s). The IRIX-A™ System is intended to be used with autograft and/or allograft comprised of cancellous and/or corticancellous bone graft material, and is to be used with three titanium alloy screws included as part of the system.

Hyperlordotic implants >20° are intended for use with supplemental fixation (e.g. facet screws or posterior fixation).

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-A™ Lumbar Integrated Fusion System

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: Charlene Brumbaugh
Regulatory Affairs Manager
Email: cbrumbaugh@X-spine.com
Telephone (937) 847-8400, ext. 2192

II. DATE PREPARED: August 28, 2017

III. 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

IV. DEVICE

Trade/Proprietary Name:	IRIX-A™ Lumbar Integrated Fusion System
Device Common Name:	Intervertebral Body Fusion Device
Regulation Number:	21 CFR §888.3080
Product Code:	OVD -- Intervertebral Fusion Device with Integrated Fixation, Lumbar [disc spacer, holds bone graft]
Regulatory Class:	Class II
Review Panel:	Orthopedic

V. PURPOSE OF THE SUBMISSION

The purpose for this submission is to add hyperlordotic angle options and to expand the Indications for Use to include the use of allograft comprised of cancellous and/or corticancellous bone graft material.

VI. PREDICATE DEVICES

- Primary: X-spine, Inc.: IRIX-A™ Lumbar Integrated Fusion System – K133947
- Additional: Globus Medical, Inc.: INDEPENDENCE® Spacers -- K152022

VII. REFERENCE DEVICES

- NuVasive, BASE Interfixated Titanium System (K170592)
- Synthes, T-PAL Spacer System (K162358)
- SeaSpine, Vu A Pod™ Prime NanoMetalene® Intervertebral Body Fusion Device (K162351)

VIII. 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 autograft and/or allograft comprised of cancellous and/or corticancellous bone graft material, and is to be used with three titanium alloy screws included as part of the system.

Hyperlordotic implants >20° are intended for use with supplemental fixation (e.g. facet screws or posterior fixation).

IX. 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 boxed 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 (Ti6AI4V) 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 spacers of the IRIX-A™ System are supplied clean and STERILE. The screws and accompanying instruments of the IRIX™-A System are provided clean and non-sterile.

The system does not contain software/firmware or electrical equipment.

X. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The technological principle for both the subject and primary predicate device is fixation in the lumbar spine for skeletally mature patients with degenerative disc disease.

As was established in this submission, the subject device, IRIX-A™ Lumbar Integrated Fusion System, is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have the same technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, and function.

XI. PERFORMANCE DATA

Nonclinical testing was performed to demonstrate that the subject IRIX-A™ Lumbar Integrated Fusion System is substantially equivalent to its primary predicate device. The following testing was performed:

- ASTM F2077: Static and dynamic compression testing
- ASTM F 2267: Subsidence
- Expulsion as recommended by FDA

The results of these studies show that the subject device meets or exceeds the performance of the predicate device and does not introduce any new risks; therefore, the system is substantially equivalent to the predicate device.

XII. CONCLUSION

The subject device, IRIX-A™ Lumbar Integrated Fusion System, has been modified to expand the Indications for Use and to expand the implant offerings to include three additional lordotic angles. Based on the indications for use, technological characteristics, performance testing, and comparison to predicate and reference devices, the subject IRIX-A™ Lumbar Integrated Fusion System has been shown to be substantially equivalent to legally marketed predicate devices.