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 (DICE) 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 (DICE) at its toll-free number (800) 638-2041 or
(301) 796-7100 or at its Internet address

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
510(k) Number (if known)

K170119

Device Name

Calix® Lumbar Spinal Implant System

Indications for Use (Describe)

The Calix® Lumbar Spinal Implant 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 allograft comprised of cancellous and/or corticocancellous bone graft, and implanted via an anterior, 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)

- [X] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY  (21 CFR 807.92)
Calix® Lumbar Spinal Implant System

Date Prepared: August 29, 2017

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. 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:  Calix® Lumbar Spinal Implant System
   Device Common Name:  Intervertebral Body Fusion Device
   Regulation Number:  21 CFR §888.3080
   Product Code:  MAX -- Intervertebral body fusion device  
   with Bone Graft, Lumbar
   Regulatory Class:  Class II with Special Controls
   Review Panel:  Orthopedic
IV. PREDICATE DEVICES

- Primary: X-spine, Inc.: Calix® Lumbar Spinal Implant System (K131350)
- Additional:
  - Biomet: Zyston Straight Interbody Spacer System (K112014)
  - NuVasive: CoRoent Ti-C System (K160916)

V. REFERENCE DEVICES

- NuVasive Lumbar Interbody Implants (K161230)
- Alphatec Spine: Battalion Universal Spacer System (K160958)
- Globus Medical: Independence MIS Spacers (K160597)
- NuVasive® Lumbar Interbody Implants (K153782)

Additional Reference Device:
X-spine Calix™ Cervical PC Spinal Implant System (K112036) is included because it is an intervertebral body fusion device that is CP-Ti plasma coated PEEK, provided non-sterile, and manufactured using the same materials and same processes as the proposed devices in this submission.

VI. INDICATIONS FOR USE

The Calix® Lumbar Spinal Implant 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 allograft comprised of cancellous and/or corticocancellous bone graft, and implanted via an anterior, 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 X-spine Calix® Lumbar Spinal Implant System is an intervertebral fusion device for use with bone graft, designed for surgical placement between adjacent vertebrae of the lumbar spine as an adjunct to fusion.
The X-spine Calix® Lumbar Spinal Implant System is a generally hollow box or oval shaped device manufactured from Invibio PEEK-Optima™ LT1 per ASTM F2026. The device contains an array of holes located throughout its geometry as well as teeth on the superior and inferior surfaces to help prevent implant dislodgement or expulsion once placed in its desired location. The implants are available with or without a medical grade commercially pure titanium (CP Ti) plasma coating (per ASTM F1580) on the superior and inferior surfaces of the device.

The hollow center of the implant allows the device to be packed with bone graft: autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

The single use implants are supplied in several width, height and lordosis options to accommodate variations in patient anatomy and differing pathologies. The devices contain radiographic markers made from tantalum per ASTM F560 to aid in final placement verification. Plasma coated implants are provided clean and sterile. Non-plasma coated implants and instruments are provided non-sterile. All implants are intended for single use only, and should not be reused under any circumstances.

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 fixation at one or two contiguous levels (L2—S1 inclusive) in the lumbosacral spine for skeletally mature patients with degenerative disc disease.

Primary Predicate Device:

The subject device, Calix® Lumbar Spinal Implant System and the primary predicate device, Calix® Lumbar Spinal Implant System (K131350) are based on the following technological elements:

- Same FDA Product Code: MAX -- Intervertebral Body Fusion Device, Lumbar with Bone Graft.
- Same implant materials: Invibio PEEK-Optima™ LT1 with tantalum markers.
- Equivalent Indications for Use.
- Multiple lengths, widths, and heights to account for variations in patient anatomy. Same range of sizes of devices offered.
- Same anatomical region: one or two contiguous levels (L2-S1 inclusive).
- Same surgical approaches: Anterior, posterior, and/or transforaminal.
- Mechanical performance.

The subject device has two additional technological elements:

- Expansion of the Indications for Use to include the use of allograft comprised of cancellous and/or corticocancellous bone graft.
- Addition of medical-grade titanium plasma coating (CP Ti) per ASTM F1580 on the superior and inferior surfaces of the implants.
Additional Predicate Devices:

- NuVasive CoRoent Ti-C System (K160916) has the same technological elements that are listed above for the subject device and the primary predicate device. It also has the two additional technological elements that are listed referenced above, allograft and titanium plasma coating.

- Biomet Zyston Straight Interbody Spacer System (K112014) has similar technological elements to the Calix® Lumbar Spinal Implant System. It is included in this 510k for comparison of performance data.

Reference Devices:

- NuVasive Lumbar Interbody Implants (K161230)
- Alphatec Spine: Battalion Universal Spacer System (K160958)
- Globus Medical: Independence MIS Spacers (K160597)
- NuVasive® Lumbar Interbody Implants (K153782)

The above reference devices have been 510k cleared with the same or similar technological elements as included in the Calix subject device:

- Indications for Use including allograft along with autograft
- Anatomical region of one or two contiguous levels (L2—S1 inclusive)
- MAX product code
- Implant materials of PEEK and/or Titanium Alloy
- Coated with medical grade commercially pure titanium (CP Ti) plasma coating

Additional Reference Device:

- X-spine Calix™ Cervical PC Spinal Implant System (K112036) is included because it is an intervertebral body fusion device that is CP-Ti plasma coated PEEK, and manufactured using the same materials and same processes as the proposed devices in this submission.

IX. PERFORMANCE DATA

The predicate system, Calix® Lumbar Spinal Implant System (K131350), was subjected to the following mechanical testing as recommended in the special controls guidance document, “Class II Special Controls Guidance: Intervertebral Body Fusion Device”.

X-Spine Systems, Inc. 510(k) Calix® Lumbar Spinal Implant System
Therefore most of those tests were not repeated, since the size offerings and footprints of the coated implants are the same as the uncoated:

- ASTM F2077- Test Methods for Intervertebral Body Fusion Devices
- Expulsion testing as recommended by FDA
- ASTM F2267-04 Test Methods for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression

For the proposed Calix® Lumbar Spinal Implant System (with titanium plasma coated implants) testing was performed in order to demonstrate that the new titanium plasma coated implants perform as well as or better than the predicate device, Calix® Lumbar Spinal Implant System (K131350). The tests that were performed are:

- ASTM F2077 Test Methods for Intervertebral Body Fusion Devices: Dynamic Compression Shear
- Expulsion Testing as recommended by the FDA
- ASTM F1877 Standard Practice for Characterization of Particles.

The results of the testing demonstrate that the addition of the medical grade commercially pure titanium plasma coating does not present a new worst case, and does not impact the performance of the implants.

The proposed expansion of the indications for use, i.e. the addition of the use of allograft, does not impact the mechanical performance of the Calix® Lumbar Titanium Plasma Coated implants, and does not introduce new risks. Allograft has been 510k cleared for a large number of spinal implants that formerly were cleared only for autograft.

X. CONCLUSION

The subject device, Calix® Lumbar Spinal Implant System, has been modified to expand the Indications for Use, and to add medical grade commercially pure titanium (CP Ti) plasma coated versions of the original Calix® Lumbar implants. Based on the indications for use, technological characteristics, and comparison to predicate devices, the subject Calix® Lumbar Spinal Implant System demonstrates substantial equivalence to legally marketed predicate devices.