



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

X-Spine Systems, Inc.
Mr. Kriss Andersson
Director, Regulatory Affairs
452 Alexandersville Road
Miamisburg, Ohio 45342

August 1, 2017

Re: K171075

Trade/Device Name: Calix-C™ Cervical Interbody Spacer
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: May 2, 2017
Received: May 4, 2017

Dear Mr. Andersson:

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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K171075

K170175

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Device Name

Calix-C™ Cervical Interbody Spacer

Indications for Use (Describe)

The Calix-C™ Cervical Interbody Spacer is intended for spinal fusion procedures at one level (C2 – T1 inclusive) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. 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 the Calix-C™ Cervical Interbody Spacer.

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

Calix-C™ Cervical Interbody Spacer

- 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. DATE PREPARED:** May 2, 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: Calix-C™ Cervical Interbody Spacer
Device Common Name: Intervertebral Body Fusion Device
Regulation Number: 21 CFR §888.3080
Product Code: ODP -- Intervertebral body fusion device
with Bone Graft, Cervical

Regulatory Class: Class II with Special Controls
Review Panel: Orthopedic

V. PURPOSE OF THE SUBMISSION

The purpose for this submission is to add additional sizes of Calix implants to the system, now known as Calix-C™ Cervical Interbody Spacer and to expand the Indications for Use.

VI. PREDICATE DEVICES

- Primary: X-spine, Inc.: Calix PC™ Spinal Implant System -- K112036
- Additional: Globus Medical, Inc.: PATRIOT® Cervical Spacers, (including COLONIAL® and COLONIAL® TPS) -- K143578
- Medtronic Sofamor Danek USA, Inc.: ANATOMIC PEEK PTC Cervical Fusion System – K160528
- Stryker Spine: AERO®-C Cervical Cage System – K152532
- Biomet Spine: C-Thru™ Anterior Spinal System – K151064

VII. INDICATIONS FOR USE

The Calix-C™ Cervical Interbody Spacer is intended for spinal fusion procedures at one level (C2 – T1 inclusive) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. 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 the Calix-C™ Cervical Interbody Spacer.

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

VIII. DEVICE DESCRIPTION

The Calix-C™ Cervical Interbody Spacer is an intervertebral fusion device, generally box or oval-shaped, that has various holes throughout its geometry. The device body is made from Invibio PEEK-Optima™ (polyetheretherketone) per ASTM F2026, with radiographic markers made from tantalum per ASTM F560. Superior and inferior surfaces of the device have teeth to help prevent implant dislodgement or expulsion once placed in its desired location. The implants are available with or without titanium plasma coating on the superior and inferior surfaces of the device. The plasma coating is made from medical-grade titanium per ASTM F1580. The hollow center of the implant allows the device to

be packed with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

The system does not contain software/firmware.

IX. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

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

As was established in this submission, the subject device, Calix-C™ Cervical Interbody Spacer, 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. This device does not contain software or electrical equipment.

X. PERFORMANCE DATA

Mechanical testing is recommended in the FDA special controls guidance document, *“Class II Special Controls Guidance: Intervertebral Body Fusion Device”*. X-spine has previously submitted to the FDA results of performance testing for Calix cervical implants: K112036 and K083637, according to the following standards:

- ASTM F2077-03 Test Methods for Intervertebral Body Fusion Devices:
 - Static and dynamic torsion testing
 - Static and dynamic axial compression and compression shear testing
- ASTM F 2267-04 Test Methods for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression
- Expulsion testing as recommended by FDA
- ASTM F 1580 -- Performance Qualification of Commercially Pure Titanium Plasma Spray (CP Ti)

Therefore, no new nonclinical testing was performed for the purpose of this submission.

XI. CONCLUSION

The subject device, Calix-C™ Cervical Interbody Spacer, has been modified to expand the Indications for Use and two additional footprints have been added. Based on the indications for use, technological characteristics, and comparison to predicate and reference devices, the subject Calix-C™ Cervical Interbody Spacer demonstrates substantial equivalence to legally marketed predicate devices.