March 15, 2018

X-spine Systems, Inc.
Ms. Charlene Brumbaugh
Regulatory Affairs Manager
664 Cruiser Lane
Belgrade, Montana 59714

Re: K180153
Trade/Device Name: X-spine Cortical Bone Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: January 18, 2018
Received: January 19, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180153

Device Name

X-spine Cortical Bone Screw System

Indications for Use *(Describe)*

The X-spine Cortical Bone Screw System is intended for posterior, non-cervical pedicle fixation to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine for the following indications:

- Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies
- Severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusions by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion
- Spondylolisthesis
- Trauma (i.e. fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (i.e. scoliosis, kyphosis)
- Spinal tumor
- Pseudoarthrosis, and/or
- Failed previous fusion

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)

X-spine$_{SM}$ Cortical Bone Screw System

I. SUBMITTER/MANUFACTURER:

X-spine Systems, Inc.
A Division of Xtant Medical Inc.
Corporate Office
664 Cruiser Lane
Belgrade, MT 59714

Telephone (406) 388-0480, ext. 1128

Establishment Registration Number: 3005031160

Official Contact for 510k:

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

II. DATE PREPARED: March 15, 2018

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, ext. 1106

IV. DEVICE

Trade/Proprietary Name:	X-spine$_{SM}$ Cortical Bone Screw System
Device Common Name:	Orthosis, Pedicle Screw Fixation
Regulation Number:	21 CFR §888.3070
Product Code:	NKB - thoracolumbosacral pedicle screw system
Regulatory Class:	Class II
Review Panel:	Orthopedic

V. PURPOSE OF THE SUBMISSION

The purpose for this submission is to submit a new medical device for review.

VI. PREDICATE DEVICES

Primary Predicate:

- X-spine Pedicle Screw System (K152132) [Fortex®]

Additional Predicates:

- Arsenal Spinal Fixation System (K152968) [Alphatec Spine, Inc.]
- Xia 4.5 Spinal System (K050461) [Stryker Spine]

VII. INDICATIONS FOR USE

The X-spine Cortical Bone Screw System is intended for posterior, non-cervical pedicle fixation to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine for the following indications:

- Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies
- Severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusions by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion
- Spondylolisthesis
- Trauma (i.e. fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (i.e. scoliosis, kyphosis)
- Spinal tumor
- Pseudoarthrosis, and/or
- Failed previous fusion

VIII. DEVICE DESCRIPTION

The X-spine$_{SM}$ Cortical Bone Screw System consists of pedicle screws, rods, cross connectors, and associated instruments. Various forms and sizes of these implants are available so that adaptations can be made to take into account the pathology and anatomy of an individual patient. The system implant components are manufactured from Ti6Al4V ELI, a titanium based alloy which complies with ASTM F136. Alternatively, rods are also offered manufactured from cobalt chromium alloy which complies with ASTM F1537. The single use only implants are provided non-sterile, and should not be reused under any circumstances.

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

IX. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The technological principle for both the subject and predicate devices is temporary posterior, non-cervical pedicle spinal fixation in order to provide immobilization and stabilization of spinal segments in skeletally mature patients, as an adjunct to spinal fixation.

As was established in this submission, the subject device, X-spine$_{SM}$ Cortical Bone Screw 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 or similar technological and functional characteristics as its primary predicate device and additional predicate devices, through comparison in areas including design, intended use, material composition, and technological and functional characteristics.

- FDA Product Code: NKB
- Implants use the same materials: titanium alloy and/or cobalt chrome alloy.
- Multiple lengths of pedicle screws and rods to account for variations in patient anatomy.
- Equivalent Intended Uses.
- Same anatomical region.
- Same surgical approach.
- Mechanical Performance.

X. PERFORMANCE DATA

To aid in determining mechanical basis for substantial equivalence the X-spine Cortical Bone Screw System was subjected to the following testing per FDA guidance and recommendations:

- ASTM F1717 – Static and dynamic axial compression bending testing
- ASTM F1717 – Static torsion testing

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 devices.

XI. CONCLUSION

Based on assessment of the indications for use, technological characteristics, performance data, and comparison to the primary predicate device and additional predicate devices, the subject device, X-spine$_{SM}$ Cortical Bone Screw System has been shown to be substantially equivalent to legally marketed predicate devices.