DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 6, 2017

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

Re: K170224
Trade/Device Name: Spider® Cervical Plating System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: June 1, 2017
Received: June 5, 2017

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,

Vincent J. Devlin -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)*

K170224

Device Name

Spider® Cervical Plating System

Indications for Use *(Describe)*

The Spider® Cervical Plating System is intended for anterior fixation of the cervical spine. The system is indicated for use in temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with the following: degenerative disc disease (as identified by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal tumors, deformity (e.g., kyphosis, lordosis, scoliosis), pseudarthrosis, 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY (21 CFR 807.92)

Spider® Cervical Plating System

June 27, 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: 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:	Spider® Cervical Plating System
Device Common Name:	Appliance, Fixation, Spinal Intervertebral Body
Regulation Number:	21 CFR §888.3060
Product Code:	KWQ – Spinal intervertebral body fixation orthosis
Regulatory Class:	Class II
Review Panel:	Orthopedic

IV. PREDICATE DEVICES

- Primary: X-spine, Inc.: Spider® Cervical Plating (SCP) System (K052292)
- Additional: Synthes Anterior CSLP System: (K030866)

V. INDICATIONS FOR USE

The Spider® Cervical Plating System is intended for anterior fixation of the cervical spine. The system is indicated for use in temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with the following: degenerative disc disease (as identified by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), tumors, deformity (e.g., kyphosis, lordosis, scoliosis), pseudarthrosis, and/or failed previous fusion.

VI. DEVICE DESCRIPTION

The Spider® Cervical Plating System consists of titanium alloy (Ti 6Al 4V ELI) anterior cervical plates and bone screws, allowing for fixation between one and four intervertebral segments. The plates attach to the anterior portion of the vertebral body of the cervical spine, levels C2 to C7. The titanium alloy conforms with ASTM F136, *Standard Specification Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) alloy for Surgical Implant Applications (UNS R56401).*

The system does not contain software/firmware.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The technological principle for both the Subject and Primary Predicate Devices is anterior fixation, between one and four intervertebral segments of the cervical spine, levels C2 to C7.

Primary Predicate Device:

The subject device, Spider® Cervical Plating System and the primary predicate device, Spider® Cervical Plating System (K052292) are based on the following technological elements:

- Same FDA Product Code: KWQ – Spinal intervertebral body fixation orthosis
- Same implant material: Titanium alloy (Ti 6Al 4V ELI)
- Same Indications for Use.
- Plates: same multiple lengths, widths, and heights of plates to account for variations in patient anatomy.

- Screws: same multiple lengths of screws with the exception of an additional screw length added to the Spider® Cervical Plating System subject device offerings – 18mm.
- Same anatomical region: between one and four intervertebral segments of the cervical spine, levels C2 to C7.
- Same surgical approach: Anterior

Additional Predicate Device:

An additional predicate device is Synthes Spine Anterior CSLP System, K030866. The Synthes CSLP System was the primary predicate device in the original Spider® Cervical Plating System 510k, K052292. The Synthes CSLP system has the same technological elements that are listed above for the Spider® Cervical Plating System subject device and the primary predicate device. In addition, like the subject device of this submission, the Synthes CSLP System includes screw lengths of 18mm.

VIII. PERFORMANCE DATA

Axial Pullout Testing was performed on Spider 18mm screws comparing them to Synthes screws, referencing ASTM F543, Standard Specification and Test Methods for Metallic Medical Bone Screws. The test results showed substantial equivalence between the Spider screws and the Synthes screws. The proposed 18mm Spider screw, longer by 2mm, raises no new concerns of safety or effectiveness.

IX. CONCLUSION

The subject device, Spider® Cervical Plating System, has been modified to add 18mm screws to the system. Based on the indications for use, technological characteristics, and comparison to predicate devices, the subject Spider® Cervical Plating System demonstrates substantial equivalence to legally marketed predicate devices.