Axis Orthopaedics
% Steve Brown
QA/RA Manager
CoorsTek Medical
560 W. Golf Course Rd.
Providence, Utah 84332

November 16, 2018

Re: K181140
Trade/Device Name: Axis Chena Cervical PEEK Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: October 11, 2018
Received: October 15, 2018

Dear Mr. Brown:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Katherine D. Kavlock -S

for
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): **K181140**

Device Name: Axis Chena Cervical PEEK Spacer System

Indications for Use:

The Chena Cervical Peek Spacer System is an anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level or two contiguous levels from C2-TI. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Chena Cervical Peek Spacer interior should be packed with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and implanted via an anterior approach. The Chena Cervical Peek Spacer is intended to be used with supplemental fixation.

Prescription Use___X__ AND/OR Over-the-Counter Use_____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

K181140 - 510(k) SUMMARY

Device Trade Name: Axis Chena Cervical PEEK Spacer System

Date: April 23, 2018
Sponsor: Axis Orthopaedics

Contact Person: Steve Brown

Manufacturer: Axis Orthopaedics
Common Name: Axis Chena Cervical PEEK Spacer System
Device Classification: Class II
Classification Name: Intervertebral Fusion Device with Bone Graft, Cervical
Intervertebral body fusion device
Regulation: 888.3080

Device Regulation Panel: Orthopedic

Device Product Code: ODP

Indications for Use:
The Chena Cervical Peek Spacer System is an anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level or two contiguous levels from C2-TI. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Chena Cervical Peek Spacer interior should be packed with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and implanted via an anterior approach. The Chena Cervical Peek Spacer is intended to be used with supplemental fixation.

Device Description:
The Axis Chena Cervical PEEK Spacer System consists of a variety of footprints and heights of PEEK cervical interbody spacer implants to assist in interbody fusion.

The Axis Chena Cervical PEEK Spacer System implant components are fabricated from medical implant grade Polyetheretherketone and tantalum described by such standards as ASTM F2026-17 and ASTM F560-17. Axis Orthopaedics Corporation expressly warrants that these devices are fabricated from one of the foregoing material specifications.

Do not use any of the Axis Chena Cervical PEEK Spacer System implant components with components from any other system or manufacturer. As with all orthopaedic and neurosurgical implants, none of the Axis Chena Cervical PEEK Spacer System components should ever be reused under any circumstances.

Implant Materials

Material:	Standard:
Implant Grade PEEK	ASTM F2026-17
Tantalum	ASTM F560-17

Technological Characteristics:
There are no technological characteristics that raise new issues of safety or effectiveness.

Assessment of performance data:
The AXIS Orthopaedics Chena Cervical PEEK Spacer System was designed and tested as an interbody fusion device for the cervical spine. The objective of this testing was to demonstrate that the subject AXIS device is equivalent to predicate devices with respect to testing recommended in ASTM F2077-14 and F2267-11.

Static and dynamic compression and torsion testing and subsidence testing on the subject device was performed per the applicable standards referenced above.

Legally Marketed Predicate Devices:
Primary:
DePuy Synthes ACIS – Anterior Cervical Interbody System (K120275)
Reference:
K2M Cascadia – Cervical Interbody (K162264)

Predicate Indications for Use:
Primary:
DePuy Synthes (K120275)- The Synthes ACIS System is an anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of nonoperative treatment. The interior of the Synthes ACIS should be packed with autogenous bone graft material and implanted via an anterior approach. The Synthes ACIS is intended to be used with supplemental fixation.
Reference:
K2M (K162264)- The Cascadia cervical implants are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with cervical disc disease (DDD) at one level or two contiguous levels from C2 to T1. These patients should be skeletally mature and have had six weeks of non-operative treatment. The Cascadia cervical implants are also to be used with supplemental fixation; the hyper lordotic Cascadia cervical implants (i.e,>= 10 °) are required to be used with an anterior cervical plate as the form of supplemental fixation.

Conclusion:
Based on the above information, it can be concluded that the subject device is substantially equivalent with respect to its intended use and technological characteristics.