April 5, 2018

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

Re: K173867
Trade/Device Name: Axis Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: March 22, 2018
Received: March 23, 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. 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,

Katherine D. Kavlock -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)*
K173867

Device Name
Axis Anterior Cervical Plate System

Indications for Use *(Describe)*
The Axis Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion from levels C2 through T1 of the cervical spine. The system is indicated for use in the stabilization of the anterior cervical spine during the development of cervical spinal fusion in patients. The indications include spinal stenosis, degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies,), tumors, deformity (defined by kyphosis, lordosis, or scoliosis), and/or pseudoarthrosis (defined as failed previous fusion).

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.

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510(k) SUMMARY

Device Trade Name: Axis Anterior Cervical Plate System

Date: December 8, 2017
Sponsor: Axis Orthopaedics

Contact Person: Steve Brown

Manufacturer: Axis Orthopaedics
Common Name: Axis Anterior Cervical Plate System
Device Classification: Class II
Classification Name: Spinal intervertebral body fixation orthosis
Regulation: 888.3060

Device Regulation Panel: Orthopedic

Device Product Code: KWQ

Purpose:
The purpose of this Traditional 510(k) submission is to gain clearance for the Axis Anterior Cervical Plate System.

Device Description:
Axis Anterior Cervical Plate System is a plate and screw system composed of medical grade titanium Ti-Alloy (Ti-6Al-4V ELI) components. The titanium plates are available in a variety of lengths, addressing multiple levels of fixation. The plates contain an integrated locking mechanism which interfaces with fixed and variable angled screws, of various diameters and lengths, to accommodate anatomical variation when securing the plate-screw construct to the anterior cervical vertebral bodies. The system is intended to provide mechanical support to the implanted level(s) until fusion is achieved. To accommodate normal cervical spine lordosis, and at the same time eliminate the need for additional plate contouring, Axis Anterior Cervical Plates come with a pre-lordosed curve. Various instruments are available to facilitate the implantation of the device.

Indications for Use:
The Axis Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion from levels C2 through T1 of the cervical spine. The system is indicated for use in the stabilization of the anterior cervical spine during the development of cervical spinal fusion in patients. The indications include spinal stenosis, degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies,), tumors, deformity (defined by kyphosis, lordosis, or scoliosis), and/or pseudoarthrosis (defined as failed previous fusion).

Legally Marketed Predicate Devices:
Primary:
Medtronic Atlantis Vision Anterior Cervical Plate System (K021461)
Secondary:
Exactech Ambassador Anterior Cervical Plate System (K091926 and K143576)
DePuy Synthes Vectra Anterior Cervical Plate System (K031276)

Implant Materials

Material:	Standard:
Ti-6Al-4V	ASTM F136-13

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

Assessment of performance data:

The AXIS Orthopaedics Anterior Cervical Plate system was designed as an adjunct to fusion in the cervical spine. The objective of this testing was to demonstrate that the subject AXIS device is equivalent to a predicate device with respect to testing recommended in ASTM F1717-15 and ASTM F543-13e1.

Static compressive bending, static torsion, and fatigue compression testing was performed per ASTM F1717-15 and demonstrated that the subject plate performed equivalently to the predicate device.
An engineering comparison has been provided (Appendix A) that shows a geometric comparison between the subject AXIS device and a mechanical predicate (Exactech Ambassador). Additionally, the subject screws performed sufficiently to pass the evaluation criteria set forth in the protocol that was derived from the applicable ASTM standard.

Conclusion:
Based on the above information, it can be concluded that the subject device is substantially equivalent with respect to its mechanical performance, to the mechanical predicate.