Pioneer Surgical Technology, Inc.
Jaclyn Holli
Sr. Specialist, Regulatory Affairs
375 River Park Circle
Marquette, Michigan 49855

June 23, 2021

Re: K211408
Trade/Device Name: CervAlign ® 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: May 5, 2021
Received: May 6, 2021

Dear Jaclyn Holli:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211408

Device Name

CervAlign® Anterior Cervical Plate System

Indications for Use *(Describe)*

The CervAlign Anterior Cervical Plate System is intended for anterior cervical fixation (C2-C7) for the following conditions: degenerative disc disease (DDD) defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudarthrosis, and 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

As required by 21 CFR 807.92

Company:	Pioneer Surgical Technology, Inc. 375 River Park Circle Marquette, MI 49855, USA Phone: +1-906-226-9909 Fax: +1-906-226-4443
Submitter/Contact:	Jaclyn Holli Sr. Specialist, Regulatory Affairs Pioneer Surgical Technology, Inc. jholli@rtix.com
Date Prepared	May 5, 2021
Proprietary Name	CervAlign® Anterior Cervical Plate System
Common Name	Anterior Cervical Plate System
Classification	Class II; 21 CFR 888.3060 (Product Code KWQ – Appliance, Fixation, Spinal Intervertebral Body) Spinal Intervertebral Body Fixation Orthosis
Panel	Orthopedic Device Panel
Predicate Device	CervAlign Anterior Cervical Plate System (K183060 cleared January 17, 2019) – Pioneer Surgical Technology, Inc.
Device Description	The CervAlign Anterior Cervical Plate System is designed to promote cervical fusion by providing temporary resistance to flexion, extension, lateral bending, and axial rotation with strength and stiffness in the cervical spine (C2-C7). The system includes implants of various sizes of screws and plates to accommodate varying patient anatomies. The plates have integrated cover-style locking mechanisms that actuate to cover each screw. Implants are manufactured from titanium alloy, Ti-6Al-4V ELI (ASTM F136). The implants are supplied with instrumentation necessary to facilitate the insertion and removal. The implants and instruments are provided non-sterile and must be sterilized before use. Sterilization cases and trays are provided to facilitate proper sterilization and storage.
Indications for Use	The CervAlign Anterior Cervical Plate System is intended for anterior cervical fixation (C2-C7) for the following conditions: degenerative disc disease (DDD) defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudarthrosis, and failed previous fusion.
Non-clinical Performance Data	Performance testing showed that the mechanical strength of the subject system is equivalent to or better than predicate devices and is therefore sufficient for the intended use. <u>Mechanical Testing:</u> • Locking Mechanism Retention There is no impact to the following non-clinical performance data that was included in cleared submission K183060. This testing is not included in the subject submission:

	• Mechanical Testing
	  o ASTM F1717-18 static and dynamic compression bending
	  o ASTM F1717-18 static torsion
	• MR Safety Evaluation determined the devices are MR Conditional via the following standards:
	  o ASTM F2052-15, "Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment"
	  o ASTM F2213-17, "Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment"
	  o ASTM F2182-19e2, "Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging"
	  o ASTM F2119-07 (Reapproved 2013), "Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants"
	  o ASTM F2503-20 "Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment"
	• Packaging and sterilization testing and evaluations
	• ISO 10993-1 Biological safety evaluation

Clinical Performance Data	No clinical performance data was required for a determination of substantial equivalence.
Summary of Technological Characteristics:	The subject system has the same or similar fundamental technology (technological characteristics, indications for use, material, principles of operation, overall implant geometry and size options, and anatomical location of use) as the predicate.
Substantial Equivalence	The supporting evidence in this submission is sufficient to justify the substantial equivalence of the subject CervAlign Anterior Cervical Plate System as compared to the predicate device referenced.