Pioneer Surgical Technology, Inc D.B.A Resolve Surgical Tech
Alicia Kaufman
Sr. Regulatory Affairs Specialist
375 River Park Circle
Marquette, Michigan 49855

June 20, 2023

Re: K230993
Trade/Device Name: CODA™ 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 23, 2023
Received: May 23, 2023

Dear Alicia Kaufman:

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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2023.06.20 13:24:11 -04'00'

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.

Submission Number *(if known)*

K230993

Device Name

CODA™ Anterior Cervical Plate System

Indications for Use *(Describe)*

The CODA™ Anterior Cervical Plate System is intended for anterior cervical fixation of the cervical spine (C2-C7) as an adjunct to fusion in skeletally mature patients. Specific indications include: 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, pseudoarthrosis, 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.

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

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510(k) Summary

Prepared on: 2023-05-02

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Pioneer Surgical Technology, Inc. (D.B.A Resolve Surgical Technologies)
Applicant Address	375 River Park Circle Marquette MI 49855 United States
Applicant Contact Telephone	763-772-6137
Applicant Contact	Mrs. Alicia Kaufman
Applicant Contact Email	akaufman@resolvesurg.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	CODA™ Anterior Cervical Plate System
Common Name	Spinal intervertebral body fixation orthosis
Classification Name	Appliance, Fixation, Spinal Intervertebral Body
Regulation Number	888.3060
Product Code	KWQ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K222493	CODA™ Anterior Cervical Plate System	KWQ

Device Description Summary

21 CFR 807.92(a)(4)

The CODA™ Anterior Cervical Plate (ACP) System is intended for anterior fixation of the cervical spine (C2-C7) as an adjunct to fusion in skeletally mature patients. The system consists of non-sterile and sterile, single use plates and screws that are manufactured from titanium alloy (Ti-6Al-4V ELI). The plates have an integrated active locking mechanism, are offered in various lengths, and accommodate constrained and variable screws. The system includes non-sterile, reusable instruments and sterile, single use instruments designed to facilitate proper implantation of the plate and screws.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The CODA™ Anterior Cervical Plate System is intended for anterior cervical fixation of the cervical spine (C2-C7) as an adjunct to fusion in skeletally mature patients. Specific indications include: 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, pseudoarthrosis, and failed previous fusion.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The CODA™ Anterior Cervical Plate System indications included in this Special 510(k) are the same as the CODA™ Anterior Cervical Plate System indications cleared via K222493.

Technological Comparison

21 CFR 807.92(a)(6)

The CODA™ Anterior Cervical Plate System was previously cleared via K222493. The purpose of this Special 510(k) is to introduce sterile implants to the CODA™ Anterior Cervical Plate System. Aside from the difference in sterility and packaging configuration, the subject device has the same technological characteristics as the predicate device. The summary of verification and validation activities included

in this submission supports that the sterility and packaging configuration differences do not raise issues of safety and effectiveness as compared to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Testing was conducted to show that the introduction of a sterile packaged version of the CODA™ Anterior Cervical Plate System does not impact the safety or performance. Clinical data was not necessary for the determination of substantial equivalence. Therefore, the CODA™ Anterior Cervical Plate System is substantially equivalent to the predicate device.