July 11, 2025

Pioneer Surgical Technology, Inc
Jaclyn Holli
Manager, Regulatory Affairs
375 River Park Circle
Marquette, MI 49855

Re: K251436
Trade/Device Name: Resolve 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 8, 2025
Received: May 8, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

MAZIAR SHAH-MOHAMMADI -S

[For] Brent Showalter, Ph.D.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251436

Please provide the device trade name(s).

Resolve Anterior Cervical Plate System

Please provide your Indications for Use below.

The Resolve 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #:

510(k) Summary

Prepared on: 2025-07-09

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Pioneer Surgical Technology, Inc
Applicant Address	375 River Park Circle Marquette MI 49855 United States
Applicant Contact Telephone	906-225-5617
Applicant Contact	Ms. Jaclyn Holli
Applicant Contact Email	jholli@resolvesurg.com

Device Name

21 CFR 807.92(a)(2)

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

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K211408	CervAlign Anterior Cervical Plate System	KWQ

Device Description Summary

21 CFR 807.92(a)(4)

The Resolve Anterior Cervical Plate (ACP) System is intended for anterior cervical fixation of the cervical spine (C2-C7) as an adjunct to fusion in skeletally mature patients. The system consists of non-sterile, single use plates and screws that are manufactured from titanium alloy (Ti-6Al-4V). 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 designed to facilitate proper implantation/explantation of the plates and screws.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Resolve 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)

With the exception of the addition of target population, the Resolve Anterior Cervical Plate System indications are equivalent to the primary predicate indications.

Technological Comparison

21 CFR 807.92(a)(6)

This submission utilizes the Safety and Performance Based Pathway to demonstrate substantial equivalence through performance criteria identified within FDA guidance document "Spinal Plating Systems – Performance Criteria for Safety and Performance Based Pathway." Per the guidance, a primary predicate was still identified. The Resolve Anterior Cervical Plate System is substantially equivalent

to the primary predicate technological characteristics. The Resolve Anterior Cervical Plate System was tested and compared to the acceptance criteria identified within the FDA guidance document "Spinal Plating Systems – Performance Criteria for Safety and Performance Based Pathway."

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

The following mechanical tests were performed on the subject device: static compression bending per ASTM F1717, static torsion testing per ASTM F1717, and dynamic compression bending per ASTM F1717. MR Safety analysis and testing was conducted per ASTM F2052, ASTM F2213, and ASTM F2182 to support MR Conditional Labeling.

Static compression bending, static torsion, and dynamic compression bending testing meet or exceed the acceptance criteria stated in the "Spinal Plating Systems - Performance Criteria for Safety and Performance Based Pathway" guidance document. The test results concluded that the Resolve Anterior Cervical Plate System's worst-case configuration is as safe, as effective, and performs as well as the previously cleared systems that were aggregated to inform the FDA guidance document. In addition, the MR Safety analysis and testing supports the MR Conditional labeling.