January 14, 2025

Clariance
Quang Tran
Clinical & Quality & Regulatory Affairs VP
18, rue Robespierre
Beaurains, 62217
France

Re: K243904
Trade/Device Name: Elegance® Anterior Cervical plate
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: November 29, 2024
Received: December 19, 2024

Dear Quang Tran:

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,

Ethan R. Naylor -S

for Ronald P. Jean, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243904

Device Name

Elegance® Anterior Cervical plate

Indications for Use *(Describe)*

The Elegance® Anterior Cervical plate is intended for anterior fixation to the cervical spine from C2 to C7. The specific clinical indications include:
1. Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies)
2. Spondylolisthesis
3. Spinal stenosis
4. Deformities (i.e., scoliosis, kyphosis, and/or lordosis)
5. Pseudoarthrosis
6. Revision of previous surgery

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

CLARIANCE's Elegance® Anterior Cervical plate

Submitter

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62217 Beaurains, France

Phone: + 33(0)3 21 16 12 15

Contact Person: Quang TRAN, Quality Assurance, Regulatory Affairs and Clinical VP

Date Prepared: November 29th, 2024

Name of Device: Elegance® Anterior Cervical plate

Common or Usual Name: Appliance, Fixation, Spinal Intervertebral Body

Classification Name: Spinal intervertebral body fixation orthosis, 21 CFR § 888.3060

Regulatory Class: Class II

Product Code: KWQ

Predicate Device: Aggeris™-C, CLARIANCE (K220182)

Device Description

The Elegance® Anterior Cervical plate is designed for use as a cervical plate system. The device has a shape which restores the intervertebral height and lordosis. The Elegance® Anterior Cervical plate consists in a variety of shapes and sizes of cervical plates with rounded corners, featuring bone screw's holes, locking systems and bone screws. The plates go from one (1) to five (5) levels, and the screws are self-drilling or self-tapping, and fixed or variable. The fixation is provided by the bone screws inserted into the vertebral body by means of an anterior approach. The Elegance® plates, as well as the bone screws, are made of compliant ASTM F136 Titanium alloy.

Intended Use / Indications for Use

The Elegance® Anterior Cervical plate is intended for anterior fixation to the cervical spine from C2 to C7. The specific clinical indications include:

1. Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies)
2. Spondylolisthesis
3. Spinal stenosis
4. Deformities (i.e., scoliosis, kyphosis, and/or lordosis)
5. Pseudoarthrosis
6. Revision of previous surgery

Summary of Technological Characteristics

The subject and predicate (K220182) devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicate:

- Same material (ASTM F136 Titanium alloy)
- Same plate lengths and curvatures
- Same manufacturing process.

Performance Data

The subject Elegance® Anterior Cervical plate has been tested in the following tests:

- Static Torsion Test (ASTM F1717)
- Axial Compression (ASTM F1717)
- Dynamic Compression (ASTM F1717)

The results of this non-clinical testing show that the subject Elegance® Anterior Cervical plate is substantially equivalent to legally marketed predicate device.

Conclusions

Elegance® Anterior Cervical plate has the same intended use and indications, principles of operation and similar technological characteristics as the cleared Aggeris™-C (K220182). In addition, the minor technological differences between the Elegance® Anterior Cervical plate and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that Elegance® Anterior Cervical plate is as safe and effective as the cleared Aggeris™-C (K220182). Thus, the subject Elegance® Anterior Cervical plate is substantially equivalent to the cleared Aggeris™-C (K220182).