March 30, 2022

Clariance
% Janice M. Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, 23rd Floor
Philadelphia, Pennsylvania 19103

Re: K220182
Trade/Device Name: Aggeris™-C
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: January 21, 2022
Received: January 21, 2022

Dear Janice Hogan:

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,

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 on last page

510(k) Number *(if known)*

K220182

Device Name

Aggeris™-C

Indications for Use

The Aggeris™-C device 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

CLARIANCE's Aggeris™-C

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

CLARIANCE
18 rue Robespierre
F-62217 Beaurains, France
Phone: +33 (0)3 21 16 12 15
Facsimile: +33 (0)3 21 15 50 73
Contact Person: Mélody LAPORTE, Regulatory Affairs Specialist
Date Prepared: March 28, 2022

Name of Device

Aggeris™-C

Common or Usual Name

KWQ - Appliance, Fixation, Spinal Intervertebral Body

Classification Name

§ 888.3060 Spinal intervertebral body fixation orthosis, Class II

Predicate Devices

K103491 - SKYLINE Anterior Cervical Plate - Spinal USA, Inc. (primary)

K133518 – MaxAn Anterior Cervical Plate System – Zimmer Biomet (reference)

Intended Use / Indications for Use

The Aggeris™-C device 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

Technological Characteristics

The Aggeris™-C is designed for use as a cervical plate. The device is manufactured from medical grade Titanium alloy. The device has a shape which restores the intervertebral height and lordosis. The device consists of a variety of bone screws and cervical plates provided in a variety of shapes and sizes of with rounded corners, bone screw holes, and a screw locking system. The plates are provided in a variety of lengths, allowing treatment from 1 to 5 levels.

The Aggeris™-C plates, as well as the bone screws, are made from Ti alloy conforming to ASTM F136.

Performance Data

Biocompatibility

CLARIANCE performed biocompatibility tests on the Aggeris™-C plate. Although the system uses established materials and manufacturing methods, confirmatory testing per ISO 10993-5 and -18 has been performed.

Sterility and Cleaning

The Aggeris™-C is provided in a non-sterile state and is intended to be sterilized by the final user. CLARIANCE performed cleaning and sterilization validation on the Aggeris™-C plate. Cleaning validation per ISO 19227 has shown acceptable limits of residues. Sterilization validation demonstrated a SAL of 10^{-6}.

Mechanical Testing

Performance testing was conducted per ASTM F1717-18. Specifically, CLARIANCE performed static and dynamic axial compression testing and static torsion testing. The results of these studies were determined to be substantially equivalent to legally marketed devices.

Substantial Equivalence

The Aggeris™-C is substantially equivalent to the Skyline Anterior Cervical Plate (K103491). The Aggeris™-C has the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate device. The minor technological differences between the Aggeris™-C and its predicate device do not raise any new questions of safety or effectiveness. In addition, performance data demonstrate that the Aggeris™-C is as safe and effective as its predicate device. Thus, the Aggeris™-C is substantially equivalent.