March 23, 2021

Aurora Spine, Inc.
℅ Jeffrey Brittan
Vice President of Product Realization
Watershed Idea Foundry
1815 Aston Ave., Suite 106
Carlsbad, California 92008

Re: K210325
Trade/Device Name: APOLLO™ Anterior Cervical Plate (ACP) System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: January 31, 2021
Received: February 4, 2021

Dear Jeffrey Brittan:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210325

Device Name
APOLLO™ Anterior Cervical Plate (ACP) System

Indications for Use *(Describe)*

The APOLLO™ Anterior Cervical Plate (ACP) System is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to T1). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with:

- Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
- Spondylolisthesis,
- Trauma (including fractures or dislocations),
- Tumors,
- Deformity (defined as kyphosis, lordosis, or scoliosis),
- Pseudarthrosis,
- Failed previous fusion,
- Spinal stenosis

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: APOLLO™ Anterior Cervical Plate (ACP) System

Company: Aurora Spine, Inc.
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Carlsbad, CA 92008
(760) 424-2004

Official Contact: Laszlo Garamszegi
CTO

Representative/ Consultant: Jeffrey Brittan
Watershed Idea Foundry
(714) 287-6780
jeffbrittan@watershedideas.com

Date Prepared: January 25, 2021

Device Name: APOLLO™ Anterior Cervical Plate (ACP) System

Common Name: Anterior Cervical Plate

Classification: Per 21 CFR as follows:
§888.3060 Spinal intervertebral body fixation orthosis
Product Code: KWQ
Regulatory Class: II
Orthopedic Review Panel

Predicate Device: Synthes Anterior Cervical Locking Plate (ACLP) System (K031276) – *Primary*

Osteomed Implantes Anterior Cervical Plate System (K151553)

Reference Device: Aurora Spine Zip MIS Interspinous Fusion System Reference Device: (K133091)

Purpose:
The purpose of this submission is to request clearance for the APOLLO™ Anterior Cervical Plate (ACP) System.

Device Description:
The APOLLO™ Anterior Cervical Plate (ACP) System is comprised of cervical plates and bone screws constructed of titanium alloy as described by ASTM F136. Plates are available in multiple levels and lengths, and screws are available in multiple diameters,

lengths, and tip configurations to accommodate variations in patient anatomy. The Integrated screw locking mechanism is used to block the screw heads after the device construct has been attached to the anterior cervical spine.

Indications for Use:
The APOLLO™ Anterior Cervical Plate (ACP) System is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to T1). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with:

- Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
- Spondylolisthesis,
- Trauma (including fractures or dislocations),
- Tumors,
- Deformity (defined as kyphosis, lordosis, or scoliosis),
- Pseudarthrosis,
- Failed previous fusion,
- Spinal stenosis

Technological Characteristics:
The plates and bone screws are manufactured from titanium alloy per ASTM F136, which has a successful history of use in the spinal implant industry and use of it in these devices does not introduce any previously unaccepted patient risks. Plates are offered in multiple levels and lengths, and screws are offered in multiple diameters, lengths, and tip configurations.

Performance Data:
Non-clinical mechanical testing was performed consisting of the following test modes:

- Static and dynamic compression bending per ASTM F1717
- Static torsion per ASTM F1717

The results of this non-clinical testing show that the strength of APOLLO™ device is sufficient for its intended use. All data indicates substantial equivalence to the predicate system. Clinical data and conclusions were not needed for this device.

Basis of Substantial Equivalence:
The APOLLO™ device has been found to be substantially equivalent to the predicate device with respect to technical characteristics, performance, and intended use. These systems offer equivalent plate/screw constructs that incorporate a screw locking mechanism. The information provided within this premarket notification supports substantial equivalence of the subject device to the predicate device.