April 6, 2020

Orthopaedic & Spine Development
% Mr. Roger White
President
Phiama, Inc.
236 McKinley Park Lane
Louisville, Colorado 80027

Re: K193494
Trade/Device Name: Origin™ 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: March 18, 2020
Received: March 20, 2020

Dear Mr. Roger White:

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.
Acting 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)*

K193494

Device Name
Origin™ Anterior Cervical Plate System

Indications for Use *(Describe)*

The Origin Anterior Cervical Plate System is intended for anterior cervical fixation (C2-T1) for the following indications: degenerative disc disease (DDD) defined as neck pain of discogenic origin with degeneration of the disc confirmed by history or radiographic studies, spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvature (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.

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510(k) Summary
Origin™ Anterior Cervical Plate System

1. Submitter Information

Submitter:	Orthopaedic & Spine Development (OSD)
Address:	Technopôle Agroparc – BP 11211 84911 Avignon Cedex 9, France
Telephone:	+33 (0)4-32-74-01-10
Telefax:	+33 (0)4-90-80-02-39
Contact:	Roger White rwhite@phiama.com 303-550-2451
Date Prepared:	December 16, 2019

2. Device Information

Trade Name:	Origin™ Anterior Cervical Plate
Common Name:	System Anterior Cervical Fixation
Classification:	System Class II per 21 CFR 888.3060
Classification Name:	Appliance, Fixation, Spinal Intervertebral Body
Product Code:	KWQ

3. Purpose of Submission

The purpose of this submission is to gain clearance for a new Anterior Cervical Fixation System.

4. Predicate Device Information

The Origin Anterior Cervical Plate System described in this submission is substantially equivalent to the following predicates:

Predicate Device	**Manufacturer**	**510(k) No.**
Trifore™ Cervical Plating System	NeuroStructures, Inc.	K171112
TERRACE™ Anterior Cervical Plate System	CoreLink	K163104

5. Device Description

Origin Anterior Cervical Plate System is an anterior cervical fixation system comprised of a titanium plate, and bone screws, both in multiple sizes. The Plate features multiple holes designed to receive and secure bone screws. The Plate System is provided non-sterile and is intended for single use.

6. Intended Use

The Origin Anterior Cervical Plate System is intended for anterior cervical fixation (C2-T1) for the following indications: degenerative disc disease (DDD) defined as neck pain of discogenic origin with degeneration of the disc confirmed by history or radiographic studies, spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvature (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

7. Comparison of Technological Characteristics

The substantial equivalence of the Origin Anterior Cervical Plate System to the predicate devices is shown by the similarity in intended use, indications for use, materials, implant dimensions, and performance.

8. Performance Data

Origin Anterior Cervical Plate System was tested in accordance with the recommendations from the *FDA Guidance for Spinal Systems 510(K) submission*. This testing included static and dynamic axial compression bending and static torsion testing. A review of the performance data demonstrates substantial equivalence to the predicate devices.

9. Conclusion

Based on the indications for use, technological characteristics, biocompatibility, performance results, and comparison to the predicates, the Origin Anterior Cervical Plate System has been shown to be substantially equivalent to the predicate devices identified in this submission and does not present any new issues of safety or effectiveness.