Evolution Spine
Todd Wallenstein
VP Regulatory/Quality
2300 N. Haskell Ave
Dallas, Texas 75204

September 30, 2021

Re: K212405
Trade/Device Name: EMERGE™ 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: July 30, 2021
Received: August 2, 2021

Dear Todd Wallenstein:

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,

for

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)*
K212405

Device Name
EMERGE™ Anterior Cervical Plate System

Indications for Use *(Describe)*
The EMERGE™ Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications: degenerative disc disease (DDD) (defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors (primary and metastatic), deformity (kyphosis, lordosis or scoliosis), failed previous fusions (pseudarthrosis), spondylolisthesis, and spinal stenosis. The EMERGE™ Anterior Cervical Plate System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

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."

EVOLUTION SPINE

510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

Company: Evolution Spine
2300 N Haskell Rd
Dallas, TX 75204

Contact: Todd Wallenstein
Evolution Spine
2300 N Haskell Ave
Dallas, TX 75204
Phone: 571-594-7409
twallenstein@evolutionspine.com

Date Prepared: July 30, 2021

Device Trade Name: EMERGE™ Anterior Cervical Plate System
Common Name: Anterior Cervical Plate System
Classification: 21 CFR §888.3060 Spinal Intervertebral Body Fixation Orthosis
Class: II
Product Code: KWQ

Primary Predicate: Evolution Spine Anterior Cervical Plate System (K173375)
Additional Predicate: None

Device Description:

The EMERGE™ Anterior Cervical Plate System consists of cervical plates offered in various sizes to accommodate a variety of spinal levels based on surgical need and anatomic requirements. The plate attaches to the anterior portion of the vertebral body of the cervical spine. The plates can be used with fixed angle or variable angle screws. The system is comprised of a Titanium Alloy (Ti-6Al-4V ELI) plates and bone screws.

Indications For Use:

The EMERGE™ Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications: degenerative disc disease (DDD) (defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors (primary and metastatic), deformity (kyphosis, lordosis or scoliosis), failed previous fusions (pseudarthrosis), spondylolisthesis, and spinal stenosis. The EMERGE™ Anterior Cervical Plate System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Substantial Equivalence:
The subject EMERGE™ Anterior Cervical Plate System has been demonstrated to be substantially equivalent with respect to indications, design, materials, function, manufacturing, and/or performance as compared to the predicate devices and as identified in Spinal Plating Systems – Performance Criteria for Safety and Performance Based Pathway Guidance document; FDA-2019-D-1647.

Performance Data:
Testing on the EMERGE™ Anterior Cervical Plate System included static compression, static torsion, and dynamic compression per ASTM F1717. The results demonstrate that the EMERGE™ Anterior Cervical Plate is substantially equivalent to the performance criteria identified in Spinal Plating Systems – Performance Criteria for Safety and Performance Based Pathway Guidance document; FDA-2019-D-1647.

Conclusion:
Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject EMERGE™ Anterior Cervical Plate System has been shown to be substantially equivalent to legally marketed predicate devices.