December 21, 2017
Evolution Spine, LLC
Mr. Douglas Davis
Chief Operating Officer
2300 N. Haskell
Dallas, Texas 75204

Re: K173375
Trade/Device Name: 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: September 15, 2017
Received: October 27, 2017

Dear Mr. Davis:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vincent J. Devlin -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K173375

Device Name
Anterior Cervical Plate System

Indications for Use *(Describe)*
The Anterior Cervical Plate System is indicated for anterior screw fixation of the cervical spine (C2-C7) as an adjunct to fusion. These implants have been designed to provide stabilization for the treatment of the following indications; degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), tumor, pseudarthrosis or 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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Anterior Cervical Plate System

Premarket Notification 510(k) Summary

DATE PREPARED	September 1st, 2017
MANUFACTURER	Evolution Spine 2300 North Haskell Avenue Dallas, TX 75204
CONTACT PERSON	Douglas Davis Vice President of Product Development 214.228-6252 ddavis@evolutionspine.com
PANEL CODE	Orthopaedics/87
CLASSIFICATION NAME	KWQ 888.3060 – Spinal Intervertebral Body Fixation Orthosis, Cervical
CLASS	Class II
COMMON NAME	Anterior Cervical Plate System (KWQ)
TRADE NAME	Anterior Cervical Plate System
PREDICATE DEVICES	Synthes Anterior CSLP System manufactured by Synthes Spine (K030866) identified as the primary predicate device Anodyne Anterior Cervical Plate System manufactured by Corelink (K121514) identified as an additional predicate device

DEVICE DESCRIPTION

The Anterior Cervical Plate System consists of self-tapping screws and plates. Screws are available in a variety of diameter-length combination. Plates are available in a variety of lengths.

INDICATIONS FOR USE

The Anterior Cervical Plate System is indicated for anterior screw fixation of the cervical spine (C2-C7) as an adjunct to fusion. These implants have been designed to provide stabilization for the treatment of the following indications: degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e.,

fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), tumor, pseudarthrosis or failed previous fusion.

MATERIALS

The Anterior Cervical Plate system is manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Documentation was provided to demonstrate that the Subject Anterior Cervical Plate System is substantially equivalent to the predicate Synthes Anterior CSLP System (K030866).
The Subject device is substantially equivalent to the predicate device in intended use, indications for use, materials, technological characteristics, and labelling.

PERFORMANCE DATA

Static compression bending and torsion, and dynamic compression bending of the worst case Anterior Cervical Plate construct was performed according to ASTM F1717. The mechanical test results demonstrated that the Subject device is substantially equivalent to the predicate devices.

CONCLUSION

The Anterior Cervical Plate System and its predicate(s) have the same intended use, to provide mechanical stability in the cervical disc space to facilitate biologic fusion. The indications for use of the Subject device are identical to those of the predicate device. Minor differences between the Subject and predicate devices do not raise any new questions of safety or efficacy. Bench testing demonstrated that the differences do not adversely impact device mechanical performance. Based on the intended use, indications for use, technological characteristics, materials, and comparison to the predicate devices, the Subject Anterior Cervical Plate System has been shown to be substantially equivalent to legally marketed predicate devices.