Evolution Spine, LLC
Mr. Douglas Davis
Vice President of Product Development
2300 North Haskell Ave
Dallas, Texas 75204

July 6, 2018

Re: K180755
Trade/Device Name: Vail ALIF Buttress Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: June 19, 2018
Received: June 20, 2018

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 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,

Brent Showalter -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)*
K180755

Device Name
Vail ALIF Buttress Plate System

Indications for Use *(Describe)*
The Vail ALIF Buttress Plate System in conjunction with traditional rigid fixation is intended for use in spinal fusion procedures of the thoracolumbar to S1 spinal region as a means to maintain the relative position of weak bony tissue such as allografts or autografts. This device is not intended for load bearing applications.

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

I. SUBMITTER

Evolution Spine, LLC
2300 North Haskell Ave
Dallas, TX 75204

Contact person: Douglas Davis
Phone: (214) 228-6252
Date prepared: March 20, 2018

II. DEVICE

Name of the device: Vail ALIF Buttress Plate System
Common or usual name: Spinal Fixation Device
Regulation number: 21 CFR 888.3060
Classification name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ

III. PREDICATE DEVICE

Black Widow Anterior Buttress Plate System (K081770) - Primary Predicate
This predicate has not been subject to a design-related recall
Fang Plate System (K090415)
This predicate has not been subject to a design-related recall

IV. DEVICE DESCRIPTION

The Vail ALIF Buttress Plate System is an anterior non-load bearing plate system manufactured from Titanium Alloy 6AL-4V ELI per ASTM F136. The implants are available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient.

The Vail ALIF Buttress Plate System is provided non-sterile, for single use only.

V. INDICATIONS FOR USE

The Vail ALIF Buttress Plate System in conjunction with traditional rigid fixation is intended for use in spinal fusion procedures of the thoracolumbar to S1 spinal region as a means to maintain the relative position of weak bony tissue such as allografts or autografts. This device is not intended for load bearing applications.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

At a high level, the subject and predicate devices are based on the following same technological elements:

- all devices are utilized in anterior surgical approaches to intervertebral body fusion
- all devices are fabricated from Titanium alloy meeting the specifications of ASTM F136
- all devices have an angled flanged shape
- all devices utilize spike features in conjunction with a single screw for fixation
- all devices are supplied non-sterile, intended for sterilization by moist heat by the user

The following technological differences exist between the subject and predicate devices:

- The Vail ALIF Buttress Plate System has a visible lock engaged by the surgeon for positive visual feedback during fixation.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence.

- Static Cantilever Bending
- Dynamic Cantilever Bending

The Vail ALIF Buttress Plate System met all specified criteria and did not raise new safety or performance questions. Based on the performance testing the Vail ALIF Buttress Plate System was found to have a safety and effectiveness profile that is equivalent to the predicate device.

VIII. CONCLUSIONS

The design testing performed for the Vail ALIF Buttress Plate System demonstrated that the performance of the device is substantially equivalent to the legally marketed predicate devices.