DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 20, 2017

Summit Spine
Eric Buescher
Owner
2333 Airport Rd.
Georgetown, Texas 78628

Re: K163494
Trade/Device Name: Summit Spine Channel Cervical Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: May 14, 2017
Received: May 19, 2017

Dear Mr. Buescher:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163494

Device Name
Summit Spine Channel Cervical Interbody Fusion System

Indications for Use *(Describe)*

When used as a cervical intervertebral body fusion device, the Summit Spine Channel Cervical Interbody Fusion System is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-TI disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation (e.g.anterior cervical plate)and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage

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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5. 510(K) SUMMARY

Submitter's Name:	Summit Spine LLC
Submitter's Address:	2666 Airport Road Georgetown, Texas 78628
Submitter's Telephone:	512-208-9272
Submitter's Fax:	877-329-1362
Contact Name:	Eric Buescher
Date Summary was Prepared:	June 16 2017
Trade or Proprietary Name:	Summit Spine Channel Cervical Interbody Fusion System
Common or Usual Name:	Intervertebral Fusion Device, Cervical
Classification:	Class II per 21 CFR §888.3080
Product Codes:	ODP
Classification Panel:	Orthopedic and Rehabilitation Devices Panel
Legally Marketed (predicate) device:	Eminent Spine K090064

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Summit Spine Channel Cervical Interbody Fusion System will be offered in various device configurations based on surgical approach and patient anatomy, and consist of a Summit Spine cervical interbody implant, which may be implanted as a single device via an anterior approach.

INDICATIONS FOR USE

When used as a cervical intervertebral body fusion device, the Summit Spine Channel Cervical Interbody Fusion System is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-TI disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation (e.g. anterior cervical plate) and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

TECHNICAL CHARACTERISTICS

The Summit Spine Channel Cervical Interbody Fusion System is comprised of various device configurations designed to accommodate patient anatomy and provide the surgeon with different surgical approach options.

The Summit Spine Channel Cervical Interbody Fusion System implant components are made of polyether ether ketone (Evonik Vistakeep) that conforms to ASTM F2026. Additionally, the devices contain tantalum markers (ASTM F560) to assist the surgeon with proper placement of the device. The additional implant offering being proposed has similar technological characteristics and identical indications as the currently cleared product line.

PERFORMANCE DATA

A Finite Element Analysis tool was used to validate the worst case. The FEA demonstrated that the Channel Cervical Interbody Fusion System implant with the smallest footprint and the tallest height (14mm) exhibited higher stresses under load to that of the 5mm high implant with the same footprint. The worst case was subjected to the following tests: ASTM F2077-14 Static Axial Compression, Dynamic Axial Compression, Static Torsion, Dynamic Torsion, and ASTM F2267-04(2011) Subsidence testing on the Summit Spine 14mm Cervical Cage and 5mm Cervical Cage.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that Summit Spine Interbody Fusion System is substantially equivalent to the Eminent Spine Fusion System.