August 29, 2018

Absolute Advantage Medical, LLC
% Mr. J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K181471
Trade/Device Name: ACCUFUSE Cervical System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP, KWQ
Dated: May 31, 2018
Received: June 4, 2018

Dear Mr. Webb:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Ronald P. Jean -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)*
K181471

Device Name
ACCUFUSE Cervical System

Indications for Use *(Describe)*

The ACCUFUSE Cervical System (intervertebral body fusion device) is indicated for use as an intervertebral body fusion device in skeletally mature patients at one or two contiguous levels of the cervical spine (C2-T1) to facilitate fusion in case of degenerative disc disease (DDD) defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. The ACCUFUSE Cervical System implants are placed via an anterior approach using autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft. The ACCUFUSE Cervical System implants are to be used with supplemental fixation. Patients should have at least six weeks of non-operative treatment prior to surgery.

The ACCUFUSE Cervical System (cervical plate/screws) is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to T1). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with:

•degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
•spondylolisthesis,
•trauma (i.e. fractures or dislocations),
•tumors,
•deformity (defined as kyphosis, lordosis, or scoliosis),
•pseudarthrosis,
•failed previous fusion,
•spinal stenosis

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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*5*10(k) Summary: ACCUFUSE Cervical System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	May 31, 2018
Submitted By	Absolute Advantage Medical, LLC 2731 Millbrook Road Fayetteville, NC 28303
Primary Contact	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199 Tele e-mail: jdwebb@orthomedix.net
Trade Name	ACCUFUSE Cervical System
Classification Name	• Intervertebral Body Fusion Device • Spinal Intervertebral body fixation orthosis
Common Name	• Intervertebral Fusion Device with Bone Graft, Cervical • Appliance, Fixation Spinal Intervertebral Body
Class	II
Product Code	• ODP • KWQ
CFR Section	• 21 CFR section 888.3080 • 21 CFR section 888.3060
Device Panel	Orthopedic
Primary Predicate	• Crystal, Spinal Elements, Inc. (K133218)
Additional Predicate Devices	• UNIPLATE Anterior Cervical Plate System, DePuy Spine, Inc. (K042544 / K082273 / K100070) • BAK/C Vista Interbody Fusion, Centerpulse Spine-Tech (P980048 S3) • CLSP Plate, Synthes, (K000536)
Device Description	The ACCUFUSE Cervical System consists of intervertebral body fusion devices along with cervical plates and screws used to maintain disc space distraction in skeletally mature adults requiring an intervertebral body fusion. It is designed to be used in conjunction with supplemental spinal fixation instrumentation. The implant is available in a range of footprints and heights to suit each individual's pathology and anatomical conditions of the patient. The implant has a hollow center to allow placement of autogenous bone graft to promote intervertebral body fusion. Ridges on the superior and inferior surfaces of the device help to grip the endplates and prevent implant migration and/or expulsion. The ACCUFUSE Anterior Cervical Plate is intended for anterior screw fixation of the plate to the cervical spine. The fixation construct consists of a cervical plate that is attached to the vertebral body of the cervical spine with self-tapping or self-drilling bone screws using

	an anterior approach. Plates are available in a variety of lengths addressing single level and two levels of fixation.
Materials	• PEEK per ASTM F2026 • Tantalum per ASTM F560 • Titanium alloy (Ti-6Al-4V) per ASTM F136
Intended Use	The ACCUFUSE Cervical System is used to maintain disc space distraction in skeletally mature adults requiring intervertebral body fusion of the cervical spine.
Substantial Equivalence Claimed to Predicate Devices	The ACCUFUSE Cervical System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	The ACCUFUSE Cervical System (intervertebral body fusion device) is indicated for use as an intervertebral body fusion device in skeletally mature patients at one or two contiguous levels of the cervical spine (C2-T1) to facilitate fusion in case of degenerative disc disease (DDD) defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. The ACCUFUSE Cervical System implants are placed via an anterior approach using autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft. The ACCUFUSE Cervical System implants are to be used with supplemental fixation. Patients should have at least six weeks of non- operative treatment prior to surgery. The ACCUFUSE Cervical System (cervical plate/screws) is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to T1). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with: • degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), • spondylolisthesis, • trauma (i.e. fractures or dislocations), • tumors, • deformity (defined as kyphosis, lordosis, or scoliosis), • pseudarthrosis, • failed previous fusion, • spinal stenosis
Summary of the technological characteristics compared to predicate	<u>Intended Use</u> The ACCUFUSE Cervical System and all the predicates have similar intended uses. <u>Materials</u> The ACCUFUSE Cervical System is composed of the same material as the predicate device <u>Design Features/Functions</u> The ACCUFUSE Cervical System and cited predicate devices share similar basic design features and functions. <u>Dimensions</u> The ACCUFUSE Cervical System is dimensionally similar to cited predicate devices. <u>Sterilization</u> The ACCUFUSE Cervical System is provided non-sterile and cited predicate devices are non-sterile for single use only. <u>Performance Specification</u> Mechanical testing confirmed the ACCUFUSE Cervical System demonstrated equivalent performance to the cited predicate device under the same test conditions.

Non-clinical Test Summary	The following analyses were conducted: • Static Axial Compression: Cage per ASTM F2077 • Dynamic Compression: Cage per ASTM F2077 • Static Torsion: Cage per ASTM F2077 • Dynamic Torsion: Cage per ASTM F2077 • Subsidence: Cage per ASTM F2267 • Static Axial Compression: Plate per ASTM F1717 • Dynamic Axial Compression: Plate per ASTM F1717 • Static Torsion: Plate per ASTM F1717 The results of these evaluations indicate that the ACCUFUSE Cervical System is equivalent to predicate devices.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-clinical and Clinical	Absolute Advantage Medical considers the ACCUFUSE Cervical System to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials, performance, and intended use