DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

K2M Inc.
% Karen E. Warden, PhD
BackRoads Consulting, Inc.
PO Box 566
12520 Heath Road
Chesterland, Ohio 44026

August 23, 2017

Re: K172104
Trade/Device Name: Ozark™ 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 11, 2017
Received: July 12, 2017

Dear Dr. Warden:

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 (DICE) 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 (DICE) 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,

Mark N. Melkerson -S

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 on last page.

510(k) Number *(if known)*

K172104

Device Name
Ozark™ Cervical Plate System

Indications for Use *(Describe)*

Ozark™ Cervical Plate System is indicated for use in anterior screw fixation to the cervical spine (C2-T1) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (including fractures), spinal stenosis and tumors (primary and metastatic), failed previous fusions (pseudarthrosis) and deformity (defined as scoliosis, kyphosis or lordosis).

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 8 - 510(k) Summary

Date:	11 July 2017
Sponsor:	K2M Inc. 600 Hope Pkwy. SE Leesburg, Virginia 20175 Phone: 703.777.3155
Sponsor Contact:	Nancy Giezen
510(k) Contact:	Karen E. Warden, PhD BackRoads Consulting PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Trade Name:	Ozark™ Cervical Plate System
Common Name:	Anterior cervical plate system
Regulatory Class:	Class II
Classification Name, Regulation, Product Code:	Appliance, fixation, spinal intervertebral body, 888.3060, KWQ
Device Description:	The Ozark Cervical Plate System consists of variable and fixed screws having self-tapping and self-starting tips, and one- through five-level plates. The implants are offered both sterile and non-sterile.
Intended Use:	Ozark™ Cervical Plate System is indicated for use in anterior screw fixation to the cervical spine (C2-T1) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (including fractures), spinal stenosis and tumors (primary and metastatic), failed previous fusions (pseudarthrosis) and deformity (defined as scoliosis, kyphosis or lordosis).
Materials:	The Ozark Cervical Plate System implants are manufactured from titanium alloy as described by ASTM F136 and ASTM F1472.
Primary Predicate:	Pyrenees Cervical Plate System (K2M – K152281)
Additional Predicates:	Additional: Zavation Cervical Plate System (Zavation LLC – K130030), SKYLINE® Anterior Cervical Plate System (DePuy Spine Inc. – K103491, VueLock® Anterior Cervical Plate System (Biomet Spine [nee EBI] – K023133), Cervical Spine Locking Plate (CSLP) (Synthes Spine – K030866)
Performance Data:	Mechanical testing of the Ozark Cervical Plate System constructs was performed according to ASTM F1717 and included static and dynamic compression and static torsion. The mechanical test results demonstrate that the Ozark Cervical Plate System device performance is substantially equivalent to the predicate devices.
Technological Characteristics:	The Ozark Cervical Plate System possesses the same technological characteristics as the predicate devices. These include: • design features, • material, • anatomic location and, • dimensional attributes. Therefore the fundamental scientific technology of the Ozark Cervical Plate System devices is the same as previously cleared devices.

Conclusion: The Ozark Cervical Plate System possesses the same intended use and technological characteristics as the predicate devices. Therefore the Ozark Cervical Plate System is substantially equivalent for its intended use.