December 12, 2018

K2M Inc.
% Karen E. Warden, Ph.D.
President
BackRoads Consulting, Inc.
P.O. Box 566
Chesterland, Ohio 44026

Re: K182473
Trade/Device Name: PYRENEES Cervical Plate System, BLUE RIDGE Cervical Plate System, OZARK Cervical Plate System, CAYMAN Thoracolumbar and Buttress Plate Systems
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: November 23, 2018
Received: November 23, 2018

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. 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)*
K182473

Device Name
PYRENEES Cervical Plate System, BLUE RIDGE Cervical Plate System

Indications for Use *(Describe)*

PYRENEES and BLUE RIDGE Cervical Plate Systems are 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K182473

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K182473

Device Name
CAYMAN Thoracolumbar and Buttress Plate Systems

Indications for Use *(Describe)*

The CAYMAN Buttress Plates are intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications. The CAYMAN Thoracolumbar Plates are indicated for use via the lateral or anterolateral surgical approach in the treatment of thoracic and thoracolumbar (T1-L5) spine and for use as an anteriorly placed supplemental fixation device for the lumbosacral level below the bifurcation of the vascular structures (L5-S1). The Cayman Thoracolumbar Plate System is intended to provide temporary stabilization during fusion using autograph or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities and deformities: a) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), b) pseudoarthrosis, c) spondylolysis, d) spondylolisthesis, e) fracture, f) neoplastic disease, g) unsuccessful previous fusion surgery, h) lordotic deformities of the spine, i) thoracolumbar or lumbar scoliosis, j) deformity (i.e., scoliosis, kyphosis, and/or lordosis) associated with deficient posterior elements such as that resulting from laminectomy.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date:	6 September 2018
Sponsor:	K2M Inc. 600 Hope Pkwy. SE Leesburg, Virginia 20175 Phone: 571.919.2000
Sponsor Contact:	Nancy Giezen
510(k) Contact:	Karen E. Warden, PhD BackRoads Consulting PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Trade Names:	PYRENEES Cervical Plate System, BLUE RIDGE Cervical Plate System, OZARK Cervical Plate System, CAYMAN Thoracolumbar and Buttress Plate Systems
Common Name:	Spinal Fixation Systems
Regulatory Class:	Class II
Classification Name, Regulation, Product Code:	Appliance, fixation, spinal intervertebral body, 888.3060, KWQ
Device Description:	The previously cleared K2M PYRENEES, BLUE RIDGE, OZARK and CAYMAN plate systems consist of a variety of plates and screws designed to provide support across implanted levels of the cervical, thoracolumbar and lumbosacral spine until fusion is achieved. The primary purpose of this submission is to establish an MR Conditional labeling claim for these implants. In addition, PYRENEES, BLUE RIDGE and CAYMAN components that were previously provided non-sterile are now being optionally offered as sterile packaged devices.
Intended Use:	PYRENEES and BLUE RIDGE Cervical Plate Systems: PYRENEES and BLUE RIDGE Cervical Plate Systems are 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).
	OZARK Cervical Plate System: 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).
	CAYMAN Thoracolumbar and Buttress Plate Systems: The CAYMAN Buttress Plates are intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications. The CAYMAN Thoracolumbar Plates are indicated for use via the lateral or

	anterolateral surgical approach in the treatment of thoracic and thoracolumbar (T1-L5) spine and for use as an anteriorly placed supplemental fixation device for the lumbosacral level below the bifurcation of the vascular structures (L5-S1). The Cayman Thoracolumbar Plate System is intended to provide temporary stabilization during fusion using autograph or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities and deformities: a) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), b) pseudoarthrosis, c) spondylolysis, d) spondylolisthesis, e) fracture, f) neoplastic disease, g) unsuccessful previous fusion surgery, h) lordotic deformities of the spine, i) thoracolumbar or lumbar scoliosis, j) deformity (i.e., scoliosis, kyphosis, and/or lordosis) associated with deficient posterior elements such as that resulting from laminectomy.
Materials:	The PYRENEES, BLUE RIDGE and OZARK Cervical Plate Systems and the CAYMAN Thoracolumbar and Buttress Plate Systems are manufactured from titanium alloy (ASTM F136 and ASTM F1472), titanium (ASTM F67), cobalt chrome (ASTM F1537) and nitinol (ASTM F2063). The materials used in the manufacturing of the instruments are stainless steel with some of the instruments incorporating aluminum, linen phenolic, Ultem, Radel, polypropylene, acetal copolymer, or silicone in the handles or retractor blades.
Primary Predicate:	OZARK Cervical Plate System (K2M Inc. – K172104)
Additional Predicates:	PYRENEES and BLUE RIDGE Cervical Plate Systems (K2M Inc. – K162664 and K113329, respectively), CAYMAN Thoracolumbar and Buttress Plate Systems (K2M Inc. – K131533)
Performance Data:	MR Compatibility testing per ASTM F2503 was performed. The test results demonstrate that the PYRENEES, BLUE RIDGE and OZARK Cervical Plate Systems and the CAYMAN Thoracolumbar and Buttress Plate Systems performance met the prescribed acceptance criteria. In addition, bacterial endotoxin testing (BET) was conducted in accordance with AAMI ST72:2011. The test results demonstrate that the sterile devices met the specified testing limit.
Technological Characteristics:	The PYRENEES, BLUE RIDGE and OZARK Cervical Plate Systems and the CAYMAN Thoracolumbar and Buttress Plate Systems possess the same technological characteristics as their predicate devices; no changes have been made to any of the devices. Therefore the fundamental scientific technology of the PYRENEES, BLUE RIDGE and OZARK Cervical Plate Systems and the CAYMAN Thoracolumbar and Buttress Plate Systems is the same as previously cleared devices.
Conclusion:	The PYRENEES, BLUE RIDGE and OZARK Cervical Plate Systems and the CAYMAN Thoracolumbar and Buttress Plate Systems possess the same intended use and technological characteristics as the predicate devices. Therefore the PYRENEES, BLUE RIDGE and OZARK Cervical Plate Systems and the CAYMAN Thoracolumbar and Buttress Plate Systems are substantially equivalent.