K2M, Inc.
Nancy Giezen
Manager Regulatory Affairs
600 Hope Parkway SE
Leesburg, Virginia 20175

December 14, 2017

Re: K172009
Trade/Device Name: Cascadia Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: November 15, 2017
Received: November 16, 2017

Dear Ms. Giezen:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K172009

Device Name
Cascadia Interbody System

Indications for Use *(Describe)*

The CASCADIA lumbar implants are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy. Additionally, the CASCADIA lumbar implants can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. CASCADIA lumbar implants are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine. The hyperlordotic CASCADIA lumbar implants (i.e., $\geq 20°$) should be used with anterior supplemental fixation (e.g., an anterior lumbar plate).

The CASCADIA cervical implants are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with cervical disc disease (DDD) at one level or two contiguous levels from C2 to T1. These patients should be skeletally mature and have had six weeks of non-operative treatment. The CASCADIA cervical implants are also to be used with supplemental fixation; the hyperlordotic CASCADIA cervical implants (i.e., $\geq 10°$) are required to be used with an anterior cervical plate as the form of supplemental fixation.

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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510(k) SUMMARY
Cascadia Interbody System
K2M, Inc.

Submitter

K2M, Inc.
600 Hope Parkway SE
Leesburg, VA 20175

Contact Person: Nancy Giezen
Telephone: 571 919-2168
Date Prepared: 12/13/2017

Classification

Trade Name:	Cascadia Interbody System
Common Name:	Intervertebral Fusion Device with Bone Graft
Regulatory Class:	Class II

Classification Name(s):
Intervertebral Fusion Device with Bone Graft, lumbar (21 CFR 888.3080, Product Code: MAX)
Intervertebral Fusion Device with Bone Graft, cervical (21 CFR 888.3080, Product Code: ODP)

Predicate Device(s)

Primary Predicate:

- K2M Cascadia Interbody System (K162264)

Additional Predicates:

- Nuvasive CoRoent (K141665)

Device Description

The implants consist of hollow tube structures additively manufactured from titanium alloy. The devices are available in a variety of different sizes and heights to match more closely the patient's anatomy. The purpose of the subject submission is to incorporate additional lumbar implant sizes into the system.

Function: The system functions as an intervertebral body fusion device to provide support and stabilization of the lumbar segments of the spine.

Indications For Use

The CASCADIA lumbar implants are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These

patients should be skeletally mature and have six months of nonoperative therapy. Additionally, the CASCADIA lumbar implants can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. CASCADIA lumbar implants are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine. The hyperlordotic CASCADIA lumbar implants (i.e., ≥ 20°) should be used with anterior supplemental fixation (e.g., an anterior lumbar plate).

The CASCADIA cervical implants are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with cervical disc disease (DDD) at one level or two contiguous levels from C2 to T1. These patients should be skeletally mature and have had six weeks of non-operative treatment. The CASCADIA cervical implants are also to be used with supplemental fixation; the hyperlordotic CASCADIA cervical implants (i.e., ≥ 10°) are required to be used with an anterior cervical plate as the form of supplemental fixation.

Technological Comparison to Predicate(s)
The Cascadia Interbody System implants were compared to predicate systems and the design features, materials and sizes were found to be substantially the same as these systems.

Non-Clinical Performance Evaluation
The worst case implants for the Cascadia Interbody System were previously tested and performed equally to or better than the predicate devices in static torsion, static compression, dynamic compression (ASTM F2077), subsidence (ASTM F2267) and expulsion. Engineering rationales determined that the proposed implants did not represent a new worst case for mechanical testing.

Bacterial endotoxin testing (BET) as specified in ANSI/AAMI ST72:2011 is used for pyrogenicity testing to achieve the Endotoxin limit of <20EU/Device.

Conclusion
There are no significant differences between the Cascadia Interbody System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.