October 3, 2019

K2M, Inc.
% Renee Norby
Regulatory Affairs Specialist
Stryker Spine
2 Pearl Court
Allendale, New Jersey 07401

Re: K190179
Trade/Device Name: SAHARA Stabilization System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: July 3, 2019
Received: September 3, 2019

Dear Renee Norby:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Ronald P. Jean, PhD
Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K190179

Device Name
SAHARA Stabilization System

Indications for Use *(Describe)*
The SAHARA Stabilization System 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 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy. Additionally, the SAHARA implants can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

Hyperlordotic (angles > 15°) and Lateral implants must be used with supplemental fixation (i.e., posterior pedicle screw and rod system) cleared for use in the lumbar spine, in addition to the bone screws provided. Additional supplemental fixation (i.e. pedicle screw and rod system) is needed when used as an adjunct to fusion for degenerative scoliosis. Otherwise, the SAHARA Stabilization System implants may be used as a stand-alone device, which is intended to be used with the bone screws provided.

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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2 510(k) Summary

510(k) Summary: SAHARA Stabilization System	
Submitter:	K2M, Inc.
Contact Person :	Name: Renee Norby Phone: 201-749-8074 Email: renee.norby@stryker.com
Date Prepared:	2-October-2019
Trade Name:	SAHARA Stabilization System
Common Name:	Spinal Fixation System
Proposed Class:	Class II , 21 CFR 888.3080
Classification Name:	Intervertebral Fusion Device with Integrated Fixation, Lumbar (OVD) Intervertebral Fusion Device with Bone Graft, Lumbar (MAX)
Product Code:	OVD; MAX
Predicate Devices:	Primary Predicate: SAHARA Stabilization System (K151481) Additional Predicates: MOJAVE Expandable Interbody System (K171097), Aleutian IBF System (K133614), and Cascadia Interbody System (K172941)
Device Description:	The subject of this 510(k) submission is the addition of lateral implants to the previously cleared SAHARA Stabilization System. The implants function as an expandable intervertebral body fusion device to provide support and stabilization to the lumbar segments of the spine through a lateral approach. The system includes lateral interbody devices as well as bone screws for integrated fixation. The implants are manufactured from Titanium (ASTM F67), Titanium Alloy (ASTM F136, ASTM F1472, ASTM F3001) and Cobalt Chrome (ASTM F1537). The implants contain components that are additively manufactured.
Intended Use:	The SAHARA Stabilization System 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 SAHARA implants can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

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510(k) Summary: SAHARA Stabilization System	
	Hyperlordotic (angles > 15°) and Lateral implants must be used with supplemental fixation (i.e., posterior pedicle screw and rod system) cleared for use in the lumbar spine, in addition to the bone screws provided. Additional supplemental fixation (i.e. pedicle screw and rod system) is needed when used as an adjunct to fusion for degenerative scoliosis. Otherwise, the Sahara Stabilization System implants may be used as a stand-alone device, which is intended to be used with the bone screws provided.
Summary of the Technological Characteristics	The subject SAHARA Lateral Expandable Interbody System and the predicate was shown to be substantially equivalent based on material, design, and mechanical performance.
Summary of the Performance Data	The following mechanical tests were performed: • Static Compression per ASTM F2077 • Static Compression Shear per ASTM F2077 • Static Torsion per ASTM F2077 • Subsidence per ASTM F2267 • Expulsion • Dynamic Compression per ASTM F2077 • Dynamic Compression Shear per ASTM F2077 • Dynamic Torsion per ASTM F2077
Conclusion	Based on the design features, feature comparisons, indications for use, and results of mechanical testing, the SAHARA Lateral Expandable Interbody System has demonstrated substantial equivalence to the identified predicate devices.