November 28, 2018

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

Re: K180665
Trade/Device Name: SANTORINI Corpectomy Cage System, CAPRI Corpectomy Cage System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: PLR, MQP
Dated: November 5, 2018
Received: November 6, 2018

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. 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,

Melissa Hall -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)*
K180665

Device Name
SANTORINI Corpectomy Cage System

Indications for Use *(Describe)*
SANTORINI Corpectomy Cages are vertebral body replacement devices intended for use in the cervical and thoracolumbar spine.

When used in the cervical spine (C2-T1), SANTORINI cages are intended for use in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. These cages are intended to restore integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

When used in the thoracolumbar spine (T1-L5), SANTORINI cages are intended for use to replace a collapsed, damaged, or unstable vertebral body due to tumor and trauma (i.e. fracture). These cages are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

The interior of the cages can be packed with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft as an adjunct to fusion.

When used in the thoracolumbar spine, the Santorini Corpectomy cages are intended to be used with supplemental internal fixation appropriate for the implanted level, including K2M Pedicle Screw and Hook Systems, and K2M Spinal Plate Systems.

When used in the cervical spine at one or two levels, the SANTORINI Corpectomy Cage System is intended to be used with supplemental fixation cleared by the FDA for use in the cervical spine. When used at more than two levels, supplemental fixation should include posterior fixation which is cleared by the FDA

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.

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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:

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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)*
K180665

Device Name
CAPRI Corpectomy Cage System

Indications for Use *(Describe)*
CAPRI Corpectomy Cages are vertebral body replacement devices intended for use in the cervical and thoracolumbar spine.

When used in the cervical spine (C2-T1), CAPRI Static cages are intended for use in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. These cages are intended to restore integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

When used in the thoracolumbar spine (T1-L5), CAPRI Static and Expandable cages are intended for use to replace a collapsed, damaged, or unstable vertebral body due to tumor and trauma (i.e. fracture). These cages are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

The interior of the cages can be packed with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft as an adjunct to fusion.

When used in the thoracolumbar spine, the CAPRI Static and Expandable Corpectomy cages are intended to be used with supplemental internal fixation appropriate for the implanted level, including K2M Pedicle Screw and Hook Systems, and K2M Spinal Plate Systems.

When used in the cervical spine at one or two levels, the CAPRI Static cages are intended to be used with supplemental fixation cleared by the FDA for use in the cervical spine. When used at more than two levels, supplemental fixation should include posterior fixation which is cleared by the FDA

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
SANTORINI and CAPRI Corpectomy Cage Systems

Submitter
K2M, Inc.
600 Hope Pkwy SE
Leesburg, VA 20175

Contact Person: Nancy Giezen
Telephone: (571) 919-2000
Date Prepared: 11/27/2018

Classification

Trade Name:	SANTORINI Corpectomy Cage System, CAPRI Corpectomy Cage System
Common Name:	Vertebral Body Replacement Device
Regulatory Class:	Class II

Classification Name(s):
Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060, Product Code PLR, MQP)

Predicate Device(s)
Primary Predicate:

- Globus Fortfy (K162315)

Additional Predicates:

- K2M CAPRI Corpectomy Cage System (K170055)
- Santorini Corpectomy Cage System (K171704)
- Aesculap Modulift (K172032)
- Nuvasive X Core Mini (K151651)

Device Description
The SANTORINI and CAPRI Corpectomy System implants are vertebral body replacement devices that are designed in a variety of lengths, widths and heights to match the patient's anatomy. Solid and adjustable cages are available and can be implanted via posterior, anterior or lateral approaches. The implants of the CAPRI Corpectomy Cage Systems are manufactured from Titanium (per ASTM F3001) and Cobalt Chrome (per ASTM F1537). The SANTORINI implants are made from PEEK OPTIMA LT1 (ASTM F2026) and tantalum (ASTM 560), with some components containing CP titanium (ASTM F67). The purpose of this submission is to expand the indications to include the cervical spine.

Function: The system is used to provide structural stability in skeletally mature individuals following a corpectomy or vertebrectomy.

Intended Use

SANTORINI

SANTORINI Corpectomy Cages are vertebral body replacement devices intended for use in the cervical and thoracolumbar spine.

When used in the cervical spine (C2-T1), SANTORINI cages are intended for use in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. These cages are intended to restore integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

When used in the thoracolumbar spine (T1-L5), SANTORINI cages are intended for use to replace a collapsed, damaged, or unstable vertebral body due to tumor and trauma (i.e. fracture). These cages are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

The interior of the cages can be packed with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft as an adjunct to fusion.

When used in the thoracolumbar spine, the Santorini Corpectomy cages are intended to be used with supplemental internal fixation appropriate for the implanted level, including K2M Pedicle Screw and Hook Systems, and K2M Spinal Plate Systems.

When used in the cervical spine at one or two levels, the SANTORINI Corpectomy Cage System is intended to be used with supplemental fixation cleared by the FDA for use in the cervical spine. When used at more than two levels, supplemental fixation should include posterior fixation which is cleared by the FDA

CAPRI

CAPRI Corpectomy Cages are vertebral body replacement devices intended for use in the cervical and thoracolumbar spine.

When used in the cervical spine (C2-T1), CAPRI Static cages are intended for use in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. These cages are intended to restore integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

When used in the thoracolumbar spine (T1-L5), CAPRI Static and Expandable cages are intended for use to replace a collapsed, damaged, or unstable vertebral body due to tumor and trauma (i.e. fracture). These cages are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

The interior of the cages can be packed with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft as an adjunct to fusion.

When used in the thoracolumbar spine, the CAPRI Static and Expandable Corpectomy cages are intended to be used with supplemental internal fixation appropriate for the implanted level, including K2M Pedicle Screw and Hook Systems, and K2M Spinal Plate Systems.

When used in the cervical spine at one or two levels, the CAPRI Static cages are intended to be used with supplemental fixation cleared by the FDA for use in the cervical spine. When used at more than two levels, supplemental fixation should include posterior fixation which is cleared by the FDA

Technological Comparison to Predicate(s)
The SANTORINI and CAPRI Corpectomy Cage Systems 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 SANTORINI and CAPRI Corpectomy Cage Systems were previously found equivalent to predicate devices when tested in static compression, static torsion, dynamic compression and dynamic torsion (per ASTM F2077) and subsidence per ASTM F2267.

Clinical Evaluation
Clinical data and a clinical literature review were used to support the use of the subject devices in the cervical spine. The risks of cervical use were identified and mitigated through design and surgical technique. Based on clinical literature, it was determined that the safety profile of the subject devices is equivalent to that of the predicate devices.

Conclusion
There are no significant differences between the SANTORINI and CAPRI Corpectomy Cage Systems 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.