February 24, 2022

K2M, Inc.
Renee Norby
Senior Regulatory Affairs Specialist
600 Hope Parkway SE
Leesburg, Virginia 20175

Re: K211320
Trade/Device Name: 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: February 14, 2022
Received: February 16, 2022

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,

Brent Showalter, Ph.D.
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211320

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 and Expandable 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 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 and Expandable 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: CAPRI Corpectomy Cage System	
Submitter:	K2M, Inc. 600 Hope Pkwy SE Leesburg, VA 20175
Contact Person :	Name: Renee Norby Phone: 201-725-4954 Email: renee.norby@stryker.com
Date Prepared:	April 29, 2021
Trade Name:	CAPRI Corpectomy Cage System
Common Name:	Vertebral Body Replacement Device
Proposed Class:	Class II
Classification Name:	Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060)
Product Code:	PLR, MQP
Predicate Devices:	Primary Predicate: • Stryker CAPRI Corpectomy Cage System (K180665) Additional Predicate: • Zavation Medical Products LLC - Normandy VBR System (K191423) Reference Predicates: • DePuy - Surgical Titanium Mesh (K003043) • Stryker Spine - CAPRI Thoracolumbar (K142016) • Stryker Spine - Santorini Expandable (K111294)
Device Description:	The 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. Static (titanium) and expandable (titanium and cobalt chrome) cervical cages are available and are implanted via an anterior approach. The cervical implants of the CAPRI Corpectomy Cage Systems are manufactured from Titanium (per ASTM F3001 and ASTM 136) and Cobalt Chrome (per ASTM F1537). The purpose of this Traditional 510(k) submission is to introduce a new 12x14mm cervical expandable footprint size to the previously cleared CAPRI Corpectomy Cage System. Function: The system is used to provide structural stability in skeletally mature individuals following a corpectomy or vertebrectomy.

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510(k) Summary: CAPRI Corpectomy Cage System

Intended Use:	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 and Expandable 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 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 and Expandable 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.
Summary of the Technological Characteristics	The subject device (a new expandable footprint in the CAPRI Corpectomy Cage System) shares the same materials, fundamental scientific technologies, and design characteristics as the predicate device in the CAPRI Corpectomy Cage System. The purpose of this submission is to introduce a new cervical expandable footprint size to the CAPRI Corpectomy Cage System, which retains the previously FDA cleared indications/intended use

510(k) Summary: CAPRI Corpectomy Cage System	
	and mode of operation as presented in the previous 510(K) submission, K180665.
Summary of the Performance Data	The following mechanical tests were performed: • Static Compression per ASTM F2077-18 • Dynamic Compression per ASTM F2077-18 • Static Torsion per ASTM F2077-18 • Dynamic Torsion per ASTM F2077-18 • Subsidence per ASTM F2267-04 R18 • Static Expulsion
Conclusion	Based on the design features, the use of established well known materials, feature comparisons, indications for use, and results of the mechanical testing, the new cervical expandable footprint of the CAPRI Corpectomy System has demonstrated substantial equivalence to the identified predicate.