October 26, 2020

K2M Inc.
Megan Callanan
Senior Regulatory Affairs Specialist
600 Hope Parkway SE
Leesburg, Virginia 20175

Re: K202528
Trade/Device Name: Cannulated Power Driver Attachment
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: August 31, 2020
Received: September 1, 2020

Dear Ms. Callanan:

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,

Colin O'Neill, M.B.E.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202528

Device Name
Cannulated Power Driver Attachment

Indications for Use *(Describe)*

The MESA and DENALI Spinal Systems (including ARI Staples) and the EVEREST Spinal System are cleared for the following indications:

Posterior non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumor; pseudoarthosis; and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system the Range Spinal System may also be used for the same indications as an adjunct to fusion.

Except for the ARI staples, the MESA, DENALI and EVEREST Spinal Systems are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis when used for posterior non-cervical fixation in pediatric patients. The MESA, DENALI and EVEREST Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

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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stryker

Traditional 510(k)
Cannulated Power Driver Attachment

510(k) Summary

510(k) Summary: Cannulated Power Driver Attachment	
Submitter:	K2M, Inc. 600 Hope Pkwy SE Leesburg, VA 20175
Contact Person :	Name: Megan Callanan Phone: (551)262-2429 Email: megan.callanan1@stryker.com
Date Prepared:	8/31/2020
Trade Name:	Cannulated Power Driver Attachment
Common Name:	Spinal Fixation Appliances, Instrument Accessory
Proposed Class:	Class II
Classification Name:	Thoracolumbosacral Pedicle Screw System
Regulation Number:	888.3070
Product Code:	NKB
Predicate Device:	Primary Predicate: K200666 Additional Predicates: K172724, K170496, K152632, K120434, K122845, K111478
Device Description:	This traditional 510(k) premarket notification is to introduce the Cannulated Power Driver Attachment instrument for use with Stryker Power Systems. The Cannulated Power Driver Attachment is an accessory to the Everest and Range (Mesa and Denali) pedicle screw systems intended to facilitate the insertion of pedicle screws using powered instrumentation. The Cannulated Power Driver Attachment, also referred to as the power adaptor or subject device, serves as a mechanical interface between the power driver and screwdriver instrument. When the adaptor is attached, the driver (corded and cordless) provides appropriate power to rotate screw drivers for the insertion of pedicle screws. No changes have been made to the indications for use of the associated thoracolumbar spinal implant systems Everest and Range (Mesa and Denali) Spinal Systems. The indications for use of each spinal system remain consistent with their most recent 510(k) clearance.
Intended Use	The intended use for the Cannulated Power Driver Attachment is to facilitate the placement of pedicle screws using the power technique (corded and cordless). The Cannulated Power Driver Attachment is intended for exclusive use with the Stryker Cordless and Corded Power Drivers. When the power adaptors are attached, the Stryker Power Drivers (corded and cordless) provide power to rotate screwdrivers for the insertion of pedicle screws. Pedicle screws from select Stryker Spine implant systems may be implanted in the non-cervical spine using powered (corded and cordless) instrumentation. The

	systems included are the family of Everest and Range (Mesa and Denali) Spinal Systems.
Indications for Use:	The MESA and DENALI Spinal Systems (including ARI Staples) and the EVEREST Spinal System are cleared for the following indications: Posterior non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumor; pseudoarthosis; and/or failed previous fusion. Except for hooks, when used as an anterolateral thoracic/lumbar system the Range Spinal System may also be used for the same indications as an adjunct to fusion. Except for the ARI staples, the MESA, DENALI and EVEREST Spinal Systems are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis when used for posterior non-cervical fixation in pediatric patients. The MESA, DENALI and EVEREST Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.
Summary of the Technological Characteristics	The Cannulated Power Driver Attachment has equivalent materials, fundamental scientific technologies and design compared with the predicate device. The screws are intended to be inserted manually or with Stryker's corded and cordless power drivers. The power adaptor accessory instrument assembly aids in the rotation of the bone screw to facilitate insertion.
Non-Clinical Performance Evaluation	The Cannulated Power Driver Attachment Instrument has demonstrated substantial equivalence to the predicate device. Verification and validation activities demonstrated connection of the Cannulated Power Driver Attachment to various Stryker Power Drivers does not represent a new worst case for powered pedicle screw insertion. The performance of the Cannulated Power Driver Attachment has met all acceptance criteria.
Conclusion	Based on the design features, the use of established well known materials, feature comparisons, and indications for use the subject devices have demonstrated substantial equivalence to the identified predicate devices.