October 2, 2019

Ulrich Medical USA
Hans Stover
President & CEO
5865 East State Rd.14
Chesterfield, Missouri 63005

Re: K191932
Trade/Device Name: Momentum™ Posterior Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: September 25, 2019
Received: September 26, 2019

Dear Hans Stover:

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, Ph.D.
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)*
K191932

Device Name
Momentum™ Posterior Spinal Fixation System

Indications for Use *(Describe)*

The Momentum™ Posterior Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion of the thoracolumbar and sacroiliac spine. When used as a posterior spine system, Momentum is intended for the following indications: degenerative disc disease, spinal stenosis, spondylolisthesis, spinal deformities (i.e., scoliosis, kyphosis, and/ or lordosis), trauma (i.e., fracture or dislocation), tumor, pseudoarthrosis and failed previous fusion.

In order to achieve additional levels of fixation, the Momentum Posterior Spinal Fixation System can also be connected to the neon3® universal OCT spinal stabilization system via transition rods or connectors. Please refer to the neon3 Instructions for Use for a list of indications for use.

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

Date:	18 July 2019
Sponsor:	ulrich medical USA, Inc. 18221 Edison Avenue Chesterfield, MO 63005 (636) 519-0268 Office (636) 519-0271 Fax
Sponsor Contact:	Hans Stover, President & CEO
Proposed Trade Name:	Momentum™ Posterior Spinal Fixation System
Common Name:	Posterior pedicle screw system
Device Classification:	Class II
Classification Name:	Thoracolumbosacral pedicle screw system
Regulation:	888.3070
Device Product Code:	NKB
Device Description:	The Momentum™ Posterior Spinal Fixation System consists of longitudinal members (rods), anchors (screws), connectors (rod/rod and rod/anchor) and fasteners in a variety of sizes to accommodate differing anatomic requirements.
Indications for Use:	The Momentum™ Posterior Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion of the thoracolumbar and sacroiliac spine. When used as a posterior spine system, Momentum is intended for the following indications: degenerative disc disease, spinal stenosis, spondylolisthesis, spinal deformities (i.e., scoliosis, kyphosis, and/ or lordosis), trauma (i.e., fracture or dislocation), tumor, pseudoarthrosis and failed previous fusion. In order to achieve additional levels of fixation, the Momentum Posterior Spinal Fixation System can also be connected to the neon$^{3®}$ universal OCT spinal stabilization system via transition rods or connectors. Please refer to the neon^{3} Instructions for Use for a list of indications for use.
Materials:	The Momentum™ System is manufactured from Ti-6Al-4V ELI titanium alloy (ASTM F136) and Cobalt Chrome (ASTM F1537).
Primary Predicate:	uCentum™ comprehensive posterior system (ulrich GmbH & Co. KG. – K123717)
Additional Predicates:	Tiger® Spine System (CoreLink LLC – K133369) , flamenco™ Spinal Fixation System (ulrich GmbH & Co. KG– K102853), neon$^{3®}$ universal OCT spinal stabilization clearance (ulrich GmbH & Co. KG – K161032), Diplomat® Spinal System (SIGNUS Medizintechnik GmbH – K151704)

Performance Data:

Mechanical testing of worst case Momentum™ System constructs included static and dynamic compression bending and static torsion according to ASTM F1717. In addition, tulip/shank pull-off testing was performed.

The mechanical test results demonstrate that the Momentum™ Posterior Spinal Fixation System performance is substantially equivalent to the predicate devices.

Technological Characteristics:

The Momentum™ Posterior Spinal Fixation System possesses similar technological characteristics as one or more of the predicate devices. These include:

- basic design (rod and screw configuration),
- material (titanium alloy, cobalt chrome) and
- sizes (dimensions are comparable to those offered by the predicate systems)

The fundamental scientific technology of the Momentum™ Posterior Spinal Fixation System is the same as previously cleared devices.

Conclusion:

The Momentum™ Posterior Spinal Fixation System possesses the same intended use and similar technological characteristics as the predicate devices. The Momentum™ Posterior Spinal Fixation is substantially equivalent for its intended use.