July 1, 2025

Ulrich Medical USA, Inc.
% Nathan Wright
Engineer & Regulatory Specialist
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K251719
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, PML, KWP
Dated: June 3, 2025
Received: June 4, 2025

Dear Nathan Wright:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251719

Please provide the device trade name(s).

Momentum® Posterior Spinal Fixation System

Please provide your Indications for Use below.

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.

When used in conjunction with G21 V-Steady Bone Cement, the Momentum Posterior Spinal Fixation System is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. Momentum™ Posterior Spinal Fixation System Screws augmented with G21 V-Steady Bone Cement are limited for use at spinal levels where the structural integrity of the spine is not severely compromised. Iliac screws are not intended to be used with bone cement.

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

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY

Submitter's Name:	Ulrich Medical USA, Inc.
Submitter's Address:	3700 East Plano Parkway, Suite 200 Plano, Texas 75074
Submitter's Telephone:	469-238-0800
Contact Person:	Nathan Wright, MS, RAC Empirical Technologies 1-719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	June 3, 2025
Trade or Proprietary Name:	Momentum® Posterior Spinal Fixation System
Device Classification Name:	Thoracolumbosacral Pedicle Screw System
Classification & Regulation #:	Class II per 21 CFR 888.3070, 888.3027, 888.3050
Product Code:	NKB, PML, KWP
Classification Panel:	Orthopedic – Spinal (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Momentum® Posterior Spinal Fixation System is a standard pedicle screw and rod systems designed for fixation and correction in the thoracolumbar and sacroiliac spine. This 510(k) submission adds hooks, various connectors, and monoaxial screws to the previously cleared system from K231809 and K191932.

The subject hooks are intended to provide deformity correction according to patient anatomical needs. The subject connectors are intended to provide additional options to improve stability. The subject monoaxial fenestrated screws are identical below the tulip to the previously cleared fenestrated screws with the addition of the option to use G21 V-Steady bone cement. The Momentum® Posterior Spinal Fixation System is manufactured from titanium alloy Ti-6Al-4V ELI per ASTM F136 and ISO 5832-3 and cobalt chromium Co-Cr-28Mo per ASTM F1537 and ISO 5832-12.

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.

When used in conjunction with G21 V-Steady Bone Cement, the Momentum Posterior Spinal Fixation System is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. Momentum™ Posterior Spinal Fixation System Screws augmented with G21 V-Steady Bone Cement are limited for use at spinal levels where the structural integrity of the spine is not severely compromised. Iliac screws are not intended to be used with bone cement.

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

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical or nearly the same between the subject and predicates:

- Indications for Use
- Structure and Function
- Size and Styles
- Materials of manufacture
- Sterility
- Manufacturing and biocompatibility

Mechanical Strength

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K180179	Firebird Deformity System	Orthofix Inc.	NKB	Primary
K231809	Momentum® Posterior Spinal Fixation System with G21 V-STEADY Bone Cement	Ulrich Medical USA, Inc.	PML, NKB	Additional
K191932	Momentum Posterior Spinal Fixation System	Ulrich Medical USA, Inc.	NKB	Additional
K140765	Mesa Spinal System	K2M, Inc.	NKB, OSH, MNI, MNH, KWQ, KWQ	Additional
K223273	ASTRA Spine System	SpineCraft, LLC	NKB, KWP, KWQ	Additional

PERFORMANCE DATA

The worst-case configuration for the Momentum® Posterior Spinal Fixation System was tested and shown substantially equivalent under K191932. The implant components introduced in this 510(k) submission were evaluated and tested under fatigue testing to show that no new worst-case is introduced. The following mechanical tests were completed:

- ASTM F1717 Dynamic Compression Bending

The results of this non-clinical testing show that the strength of the subject Momentum® Posterior Spinal Fixation System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the subject Momentum® Posterior Spinal Fixation System is substantially equivalent to the predicate device.