October 20, 2023

Ulrich Medical USA
% Michael Coladonato
Manager, Regulatory Affairs
MCRA LLC
803 7th Street NW
Washington, District of Columbia 20001

Re: K231809
Trade/Device Name: Momentum® Posterior Spinal Fixation System with G21 V-STEADY Bone Cement; Momentum® MIS Posterior Spinal Fixation System with G21 V-STEADY Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (Pmma) Bone Cement
Regulatory Class: Class II
Product Code: PML, NKB
Dated: September 18, 2023
Received: September 19, 2023

Dear Michael Coladonato:

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.

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

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)*
K231809

Device Name
Momentum® Posterior Spinal Fixation System with G21 V-STEADY Bone Cement

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.

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 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.

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)*
K231809

Device Name
The Momentum® MIS Posterior Spinal Fixation System with G21 V-STEADY Bone Cement

Indications for Use *(Describe)*
The Momentum® MIS 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 MIS 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 MIS 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 MIS 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.

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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510(k) Summary

Device Trade Name:	Momentum® Posterior Spinal Fixation System with G21 V-STEADY Bone Cement Momentum® MIS Posterior Spinal Fixation System with G21 V-STEADY Bone Cement
Manufacturer:	ulrich medical USA, Inc. ulrich medical USA, Inc. 3700 E Plano Parkway, STE 200 Plano, TX 75074 Office: 469.238.0800
Contact:	Mr. Michael Coladonato Manager, Regulatory Affairs MCRA, LLC 803 7th Street NW, Third Floor Washington, DC 20001 Phone: (202) 552-5800 Email: mcoladonato@mcra.com
Prepared by:	MCRA, LLC 803 7th Street, NW, 3rd Floor Washington, DC 20001 Office: 202.552.5800
Date Prepared:	October 18, 2023
Classifications:	21 CFR §888.3027, Polymethylmethacrylate (PMMA) Bone Cement
Class:	II
Product Codes:	PML, NKB
Primary Predicates:	G21 Cement, VADER® Pedicle System, icotec ag, K200596
Additional Predicates:	Additional Predicate: Momentum® Posterior Spinal Fixation System (K191932) Additional Predicate: Momentum® MIS Posterior Spinal Fixation System (K223274) Additional Predicate: BonOs® Inject Bone Cement; NEO Pedicle Screw System™, Neo Medical SA, K222256

Indications For Use:

The Momentum® Posterior Spinal Fixation System with G21 V-STEADY Bone Cement:

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 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.

The Momentum® MIS Posterior Spinal Fixation System with G21 V-STEADY Bone Cement:

The Momentum® MIS 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 MIS 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 MIS 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 MIS 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.

Device Description:
The Momentum® Posterior Spinal Fixation System, and Momentum® MIS Posterior Spinal Fixation System are standard pedicle screw and rod systems designed for fixation in the thoracolumbar and sacroiliac spine. There have been no major changes to the device since K191932, and K223274, respectively. The subject devices are identical to the previously cleared versions with the addition of the option to use bone cement (G21 V-Steady) with the fenestrated screws.

G21 V-Steady Bone Cement consists of a liquid and powder component. The powder component is constituted of PMMA beads shaped particles containing the initiator benzoyl peroxide required for starting to initiate the cement curing. The radiopacifier agent, zirconium dioxide, is necessary for the cement visibility under radiographs but it does not take part of the curing process (radical polymerization). The liquid component comprises the monomer, methylmemethylmethacrylate (MMA); dimethyl-para-toluidine (DMPT) as polymerization accelerator and hydroquinone (HQ) as stabilizer to prevent polymerization of the liquid during storage. V-STEADY bone cement has an immediate development of viscosity and thus it is a high viscosity cement that maintains its properties throughout the useful working time.

Predicate Device:
ulrich medical USA, Inc. submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the Momentum® Posterior Spinal Fixation System with G21 V-STEADY Bone Cement is substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to the predicate devices:

- *Primary Predicate:* G21 Cement, VADER® Pedicle System, icotec ag, K200596
- *Additional Predicate:* Momentum® Posterior Spinal Fixation System, ulrich Medical USA, K191932
- *Additional Predicate:* BonOs® Inject Bone Cement; NEO Pedicle Screw System™, Neo Medical SA, K222256

ulrich medical USA, Inc. submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the Momentum® MIS Posterior Spinal Fixation System with G21 V-STEADY Bone Cement is substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to the predicate devices:

- *Primary Predicate:* G21 Cement, VADER® Pedicle System, icotec ag, K200596
- *Additional Predicate:* Momentum® MIS Posterior Spinal Fixation System, ulrich Medical USA, K223274
- *Additional Predicate:* BonOs® Inject Bone Cement; NEO Pedicle Screw System™, Neo Medical SA, K222256

Performance Testing Summary:
Bone cement usability testing and screw removal testing was conducted to validate the use of the Momentum® Posterior Spinal Fixation System used with bone cement.

Substantial Equivalence:
The subject device was demonstrated to be substantially equivalent to the predicates cited above with respect to indications, design materials, function, manufacturing, and performance. The non-clinical tests performed by the company included bone cement usability testing and screw removal testing conducted to validate the use of the Momentum® Posterior Spinal Fixation System with bone cement.

Conclusion:
The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above. The Momentum® Posterior Spinal Fixation System with G21 V-STEADY Bone Cement and the Momentum® MIS Posterior Spinal Fixation System with G21 V-STEADY Bone Cement are substantially equivalent to the cited predicate devices.