May 20, 2025

Met One Technologies, LLC
Liberato Aguilar, COO
4519 Osbourne Drive Suite C
El Paso, Texas 79922

Re: K250866
Trade/Device Name: Sovereign Posterior Cervical System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG
Dated: May 19, 2025
Received: May 19, 2025

Dear Liberato Aguilar:

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,

EILEEN CADEL -S for

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)*
K250866

Device Name
Sovereign Posterior Cervical System

Indications for Use *(Describe)*
The Sovereign Posterior Cervical System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The Sovereign Posterior Cervical System is also 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 cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Sovereign Posterior Cervical System may be connected to the Xultan 5.5 system using rod-to-rod connectors or transition rods. Please refer to the individual system's Instructions for Use for a list of indications for use for each system.

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) #: K250866

510(k) Summary

Prepared on: 2025-05-16

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Met One Technologies, LLC
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Applicant Contact Telephone	915-373-3855
Applicant Contact	Mr. Evan Carbonell
Applicant Contact Email	evan@met1tech.com
Correspondent Name	Met One Technologies, LLC
Correspondent Address	4519 Osbourne Drive Suite C El Paso TX 79922 United States
Correspondent Contact Telephone	915-892-6044
Correspondent Contact	Mr. Liberato Aguilar
Correspondent Contact Email	libe@met1tech.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Sovereign Posterior Cervical System
Common Name	Posterior cervical screw system
Classification Name	Posterior Cervical Screw System
Regulation Number	888.3075
Product Code(s)	NKG

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K131833	Centurion POCT System	NKG
K162575	Z-LINKPC System	NKG
K142838	Synapse Occipital-Cervical-Thoracic (OCT) System	NKG
K192013	VERTICALE Cervical System	NKG
K170108	Xultan 5.5 Pedicle Screw System	NKB

Device Description Summary

21 CFR 807.92(a)(4)

The Met One Technologies Sovereign Posterior Cervical System is an implant device designed for the posterior stabilization of the

cervical and upper thoracic spine. The system includes implants such as polyaxial screws, blocker screws, rods, crosslinks, lateral connectors, and rod to rod connectors to form a unique construct to match patient anatomy.

Polyaxial screws are offered in a range of sizes in both standard and reduction tulips for ease of use. All screws are manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136).

Straight, pre-bent, and transition rods are offered in 3.5mm and 4.0mm diameters and in two different materials, titanium alloy (Ti-6Al-4V ELI per ASTM F136) and cobalt chrome (Co-Cr28-Mo6 per ASTM F1537). Transition rods are fully compatible with Met One Technologies Xultan 5.5 Pedicle Screw System line of implants.

A variety of connectors and crosslinks are offered for surgeons to create the desired construction. Rod to rod crosslinks improve the torsional stability of the construct. Lateral connectors are provided in open and closed configurations, 3.5mm and 4.0mm diameters, and in long and short lengths. Rod to rod connectors are offered in several configurations to join rods together. All connectors are manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136).

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Sovereign Posterior Cervical System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The Sovereign Posterior Cervical System is also 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 cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Sovereign Posterior Cervical System may be connected to the Xultan 5.5 system using rod-to-rod connectors or transition rods. Please refer to the individual system's Instructions for Use for a list of indications for use for each system.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The Sovereign Posterior Cervical System has identical or similar indications for use as the primary and additional predicate devices.

Technological Comparison 21 CFR 807.92(a)(6)

The Sovereign Posterior Cervical System has similar technological characteristics, surgical approach, materials, range of sizes, design, and principles of operation as the predicate devices. Any differences in technological characteristics do not raise different questions of safety or effectiveness. Performance testing demonstrates the device has mechanical performance substantially equivalent to that of the predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Mechanical testing was performed to demonstrate substantial equivalence using ASTM F1717 static compression bending, dynamic compression bending, and static torsion testing and ASTM F1798 static axial gripping capacity and static torsional gripping capacity.

The results of the mechanical testing showed that the worst-case constructs were substantially equivalent to legally marketed predicate devices.