December 4, 2025

SC Medica
% Palmer Smith
Senior Associate, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, District of Columbia 20001

Re: K250679
Trade/Device Name: FFX Facet Fixation System
Regulatory Class: Unclassified
Product Code: MRW
Dated: October 27, 2025
Received: October 29, 2025

Dear Palmer Smith:

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

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)*
K250679

Device Name
FFX Facet Fixation System

Indications for Use *(Describe)*
FFX is a facet system that is placed bilaterally through a posterior surgical approach and spans the facet interspace with the components FFX screw through the component FFX facet cage. Please refer to the Instructions for Use for the device size listings intended for cervical and lumbar use.

FFX is intended to provide temporary fixation and stabilization to the spine as an aid to lumbar fusion through bilateral immobilization of the facet joints at one or two levels with autogenous and/or allogenic bone graft. FFX is indicated for the treatment of patients with lumbar degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies and/or degenerative disease of the facet with instability from L3 to S1 in skeletally mature patients who have failed conservative care.

FFX is intended to provide temporary fixation and stabilization to the cervical spine as an adjunct to posterior cervical fusion (PCF) through bilateral immobilization of the facet joints and is only intended to be used in combination with an anterior cervical discectomy and fusion (ACDF), at the same level(s), in up to 3 consecutive levels of the cervical spine (C3-C7). FFX is indicated for skeletally mature patients with degenerative disc disease (DDD). DDD is defined as radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies. FFX is to be used with autogenous bone and/or allogenic bone graft.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Device Trade Name:	FFX Facet Fixation System
Manufacturer:	SC Medica 3 Quai Kléber – Tour Sébastopol 67000 Strasbourg – France
Contact:	Palmer Smith Senior Associate, Regulatory Affairs MCRA, LLC 803 7th Street NW Washington, DC 20001 psmith@mcra.com
Prepared by:	MCRA, LLC 803 7th Street, NW, 3rd Floor Washington, DC 20001 Office: 202.552.5800
Date Prepared:	October 28th, 2025
Classifications:	Unclassified
Class:	II
Product Codes:	MRW
Primary Predicate:	Providence Medical Technology, Inc., PMT Posterior Cervical Stabilization System (PCSS) (K241035)
Additional Predicate:	SC Medica, FFX Facet Fixation System (K252153)

Indications For Use:
FFX is a facet system that is placed bilaterally through a posterior surgical approach and spans the facet interspace with the components FFX screw through the component FFX facet cage. Please refer to the Instructions for Use for the device size listings intended for cervical and lumbar use.

FFX is intended to provide temporary fixation and stabilization to the spine as an aid to lumbar fusion through bilateral immobilization of the facet joints at one or two levels with autogenous and/or allogenic bone graft. FFX is indicated for the treatment of patients with lumbar degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies and/or degenerative disease of the facet with instability from L3 to S1 in skeletally mature patients who have failed conservative care.

FFX is intended to provide temporary fixation and stabilization to the cervical spine as an

adjunct to posterior cervical fusion (PCF) through bilateral immobilization of the facet joints and is only intended to be used in combination with an anterior cervical discectomy and fusion (ACDF), at the same level(s), in up to 3 consecutive levels of the cervical spine (C3-C7). FFX is indicated for skeletally mature patients with degenerative disc disease (DDD). DDD is defined as radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies. FFX is to be used with autogenous bone and/or allogenic bone graft.

Device Description:
The FFX Facet Fixation System consists of an FFX cage and an FFX screw.

The FFX cage is a sterile, single patient use, long-term implantable device made of titanium.

The FFX screw is a compressive screw made of titanium (EN ISO 5832-3). It is provided sterile and intended for long-term implantation.

The purpose of this 510(k) is to expand the indications for use of the system to include use in the cervical spine.

Predicate Device:
SC Medica submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, FFX is substantially equivalent in indications, design principles, and performance to the following predicate device, which has been cleared by FDA:

Primary Predicate: Providence Medical Technology, Inc., PMT Posterior Cervical Stabilization System (PCSS) (K241035)

Additional Predicate: SC Medica, FFX Facet Fixation System (K252153)

Performance Testing Summary:
To support clearance of the subject device, SC Medica completed non-clinical and clinical testing. The non-clinical testing data submitted and relied upon to demonstrate substantial equivalence included biocompatibility, sterilization validation, and bench testing (static and dynamic shear per ASTM F2077). Additionally, clinical data were submitted to further demonstrate the safety and performance of the device as compared to legally marketed predicate devices.

Substantial Equivalence:
The subject device was demonstrated to be substantially equivalent to the primary predicate, the PMT PCSS with respect to intended use, principles of operation, indications for use, design, materials, and performance.

The subject device and primary predicate both provide fixation and stabilization as an adjunct to spinal fusion. Both devices are provided in multiple size options to accommodate a range of patients. The FFX and predicate device use similar materials and are intended for single-patient and single-use.

Conclusion:
The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are manufactured from similar materials. The data included in this submission demonstrates substantial equivalence to the predicate device listed above.