October 16, 2025

SC Medica
% Justin Eggleton
Vice President, Head of Musculoskeletal Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, District of Columbia 20001

Re: K252153
Trade/Device Name: FFX Facet Fixation System
Regulatory Class: Unclassified
Product Code: MRW
Dated: September 16, 2025
Received: September 16, 2025

Dear Justin Eggleton:

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.	K252153

Please provide the device trade name(s).

FFX Facet Fixation System

Please provide your Indications for Use below.

FFX is a lumbar facet system that is placed bilaterally through a posterior surgical approach and spans the facet interspace with the component FFX screw through the component FFX facet cage. 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.

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

Device Trade Name: FFX Facet Fixation System

Manufacturer:
SC Medica
3 Quai Kléber – Tour Sébastopol
67000 Strasbourg – France

Contact:
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Prepared by:
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Date Prepared: October 15, 2025

Classifications: Unclassified

Class: II

Product Codes: MRW

Primary Predicate: SC Medica FFX (K232468)

Additional Predicate: PMT Facet Fixation System, Lumbar (PMT FFS-LX) (K230840)

Indications For Use:

FFX is a lumbar facet system that is placed bilaterally through a posterior surgical approach and spans the facet interspace with the component FFX screw through the component FFX facet cage. 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.

Device Description:
The FFX Facet Fixation system consists of an FFX Cage and an FFX Facet Screw.

The cage component of the FFX implant is a sterile, single patient use, long-term implantable device made of titanium. The cage has a D-shape that is designed to be packed with autogenous and/or allogenic bone graft. The top and bottom surfaces of the cage have teeth to improve fixation to the bone. The cage contains a bullet nose to ease insertion.

FFX Cages are titanium devices available in several sizes to ensure proper fit in the facet joint space. The implant is positioned between the facet joints, with its apex oriented anteriorly. The cage is surgically placed in the facet joint in combination with autogenous and/or allogenic bone graft material inside and posterior to the implant. Two devices are used per level with the FFX screw through the cage lumen. They are implanted between the two facets to be stabilized and can contain autogenous and/or allogenic bone graft.

The FFX Facet Screw is a self-compressive, self-tapping, headless and cannulated screw with a continuous progressive thread. It is made of titanium alloy (EN ISO 5832-3). It is provided sterile and intended for long-term implantation.

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 Facet Fixation System is substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been cleared by FDA:

Primary Predicate: SC Medica FFX (K232468)
Additional Predicate: PMT Facet Fixation System, Lumbar (PMT FFS-LX) (K230840)

Performance Testing Summary:
To support clearance of the subject device, SC Medica completed bench and clinical testing. The non-clinical testing data submitted and relied upon to demonstrate substantial equivalence included sterilization, cytotoxicity, shelf-life, and mechanical testing (e.g., static torsion, driving torque, and axial pullout per ASTM F543). 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 and additional predicates, with respect to intended use, principles of operation, and performance.

Conclusion:
The subject device and the primary predicate device have similar indications, intended use, technological characteristics, and are manufactured from 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 primary predicate device listed above. FFX Facet Fixation System is substantially equivalent compared to the primary predicate device.