May 9, 2024

SC Medica
% Justin Eggleton
Vice President, Head of Musculoskeletal Regulatory Affairs
MCRA
3 Quai Kleber - Tour Sebastopol
Strasbourg, 67000
France

Re: K232468
Trade/Device Name: SC Medica FFX
Regulatory Class: Unclassified
Product Code: MRW
Dated: April 10, 2024
Received: April 10, 2024

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.

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)*
K232468

Device Name
SC Medica FFX

Indications for Use *(Describe)*

SC Medica FFX is a lumbar facet device that is placed bilaterally through a posterior surgical approach and spans the facet interspace. SC Medica FFX must be used with an FDA-cleared transfacet screw cleared for use in the lumbar spine. SC Medica 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. SC Medica FFX must be accompanied with an FDA-cleared intervertebral body fusion device and/or with an FDA-cleared posterior lumbar pedicle screw and rod system implanted at the same spinal level(s) as an adjunct to a single or two-level intervertebral body or posterolateral fusion, respectively. SC Medica FFX is indicated for the treatment of patients with lumbar degenerative disc disease (DDD) from L3 to S1 in skeletally mature patients who have failed conservative care.

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: SC Medica FFX

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

Contact:
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Prepared by:
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Date Prepared: May 8, 2024

Classifications: Unclassified

Class: II

Product Codes: MRW

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

Additional Predicate: SurGenTec Ion Facet Screw System (K211855)

Indications For Use:
SC Medica FFX is a lumbar facet device that is placed bilaterally through a posterior surgical approach and spans the facet interspace. SC Medica FFX must be used with an FDA-cleared transfacet screw cleared for use in the lumbar spine. SC Medica 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. SC Medica FFX must be accompanied with an FDA-cleared intervertebral body fusion device and/or with an FDA-cleared posterior lumbar pedicle screw and rod system implanted at the same spinal level(s) as an adjunct to a single or two-level intervertebral body or posterolateral fusion, respectively. SC Medica FFX is indicated for the treatment of patients with lumbar

degenerative disc disease (DDD) from L3 to S1 in skeletally mature patients who have failed conservative care.

Device Description:
FFX implants are intended to provide temporary fixation and stabilization to the spine as an aid to lumbar fusion through bilateral immobilization of the facet joints. The FFX implant is a sterile, single patient use, long-term implantable device made of titanium.

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 devices, which have been cleared by FDA:

Primary Predicate: PMT Facet Fixation System, Lumbar (PMT FFS-LX) (K230840)
Additional Predicate: SurGenTec Ion Facet Screw System (K211855)

Performance Testing Summary:
To support substantial equivalence of the subject device compared to predicates, SC Medica provided non-clinical bench testing as well as clinical data. The non-clinical testing included sterilization, biocompatibilty, shelf-life, and mechanical testing (e.g., static and dynamic compression shear testing per ASTM F2077). The clinical data demonstrated a substantially equivalent safety and effectiveness profile for use at one or two consecutive levels when used in combination with an FDA-cleared intervertebral body fusion device and/or with an FDA-cleared posterior lumbar pedicle screw and rod system implanted at the same spinal level(s) as an adjunct to a single or two-level intervertebral body or posterolateral fusion, respectively. Please see indications for use statement for complete cleared indications.

Substantial Equivalence:
The subject device was demonstrated to be substantially equivalent to the primary predicate, the PMT Facet Fixation System (PMT FFS-LX, K230840), with respect to intended use, principles of operation, and performance.

The subject device and primary predicate both serve to provide temporary fixation and stabilization to the spine as an aid to lumbar fusion through bilateral immobilization of the facet joints. Both devices are provided in multiple size options to accommodate a range of patients. The FFX and predicate device use similar sterilization methods and are intended for single-patient and single-use.

Further, non-clinical data and additional clinical data demonstrate the safety and performance of the subject device is substantially equivalent to that of the predicate device.

Conclusion:
The subject device and the primary predicate device has the same indications, same intended use, have similar 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.