January 29, 2026

McNicoll Surgical, Inc.
Etienne Robichaud
Chief Executive Officer
702-1750 Ave. De Vitre
Quebec City, QC G1J1Z6
Canada

Re: K253611
Trade/Device Name: Falco Fusion System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR
Dated: November 10, 2025
Received: November 18, 2025

Dear Etienne Robichaud:

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,

MAZIAR SHAH-MOHAMMADI -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

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.	K253611

Please provide the device trade name(s).

Falco Fusion System

Please provide your Indications for Use below.

The Falco Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroilittis.

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
Falco Fusion System – Sacroiliac Joint Fusion System

Submitted By: McNicoll Surgical Inc.
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510(k) Contact: Etienne Robichaud
CEO
EtienneRobichaud@mcnicollsurgical.com

Date Prepared:	November 10th, 2025
Trade Name:	Falco Fusion System
Common Name:	Sacroiliac Joint Fusion System
Classification:	OUR, CFR 888.3040, Class II
Primary Predicate:	Outlet Sacroiliac Joint Fusion System (K181881)
Additional Predicates:	Blue Topaz Sacroiliac Screw System (K213590) Life Spine SIMPACT Sacroiliac Joint Fixation System (K201538)

Device Description:

The Falco Fusion System is designed to stabilize or fuse the sacroiliac (SI) joint, helping to reduce pain and improve mobility in patients suffering from SI joint disruptions or degenerative sacroiliitis. The system includes titanium alloy screws (Ti-6Al-4V ELI, ASTM F-136) in diameters of 11mm and 13mm, with lengths ranging from 35mm to 75mm. Additionally, the system comes with disposable Kirschner wires (316-LVM, ASTM F138) and reusable surgical (Stainless Steel, ASTM F899) instruments, providing a comprehensive solution for sacroiliac joint fusion procedures.

Indications for Use:

The Falco Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Technological Characteristics:

Falco Fusion implants are cannulated, fully threaded screw with fenestration. It features dual-pitch, self-drilling, and self-tapping screws for efficient bone purchase without the need for pilot hole drilling. Typically, 2 to 4 screws are implanted across the sacroiliac joint to achieve stabilization and fusion.

The subject device has similar technological characteristics to the predicate device, including indications for use, design, materials, and principles of operation. Differences, if any, do not raise new questions of safety or effectiveness and have been evaluated through bench testing.

Material:

The implants are made from Ti-6Al-4V ELI titanium alloy (ASTM F136) and are intended for long-term implantation. Kirschner wires are made from 316-LVM stainless steel (ASTM F138) and are single-use. Instruments are manufactured from medical-grade stainless steel (ASTM F899) and silicone (USP Class VI for handles) and are intended for reuse following steam sterilization.

The system is delivered non-sterile, and all implants and instruments are organized in a reusable instrument tray with screw caddies. Screws and Kirshner wires are replaced after each use.

Performance Data:

To support substantial equivalence, the Falco Fusion System underwent a series of non-clinical performance tests. Mechanical testing included:

- Axial pull-out strength (ASTM F543)
- Driving torque (ASTM F543)
- Torsional properties (ASTM F543)
- Static and dynamic cantilever bending (ASTM F2193)

All testing met predetermined acceptance criteria and demonstrated that the subject device performs comparably to the predicate. Although testing was performed per ASTM F543 and F2193, the device design and testing approach were also reviewed against the recommendations in ASTM F3574-22, and the system is compliant with applicable elements of that standard.

The system and associated Class II accessories/instruments undergo validated passivation and final cleaning processes. Passivation of the titanium alloy implants is performed in accordance with ASTM F86, while passivation of the stainless steel Class II instruments (e.g., guide wires) is performed in accordance with ASTM A967. Final cleaning validation for the subject device system is performed per ISO 19227. These processes support the biocompatibility assessment conducted in accordance with ISO 10993-1.

The system is delivered non-sterile. Validated steam sterilization instructions are provided in the labeling for end-user processing. Reusable instruments were validated for cleaning and sterilization in accordance with ANSI/AAMI ST98:2022.

Substantial Equivalence:

The Falco Fusion System has the same intended use and similar technological characteristics as the predicate device. Performance testing, including mechanical evaluation and reprocessing validation, demonstrates the device is as safe and effective as the predicate.

Any differences do not raise new questions of safety or effectiveness. The device is therefore substantially equivalent to the predicate.

Predicate Devices:

510(k) #	Device Name	Manufacturer	Product Code	Type
K181881	Outlet Sacroiliac Joint Fusion System	SIJ Surgical	OUR	Primary
K201538	Life Spine SIMPACT Sacroiliac Joint Fixation System	Life Spine Inc.	OUR, HWC	Additional
K213590	Blue Topaz Sacroiliac Screw System	Osseus Fusion Systems, LLC	OUR	Additional

Conclusion:

Based on the indications for use, technological characteristics, and non-clinical performance testing, the Falco Fusion System is substantially equivalent to the predicate device and does not raise new questions of safety or effectiveness