October 3, 2022

Aurora Spine, Inc.
% Samuel Pollard
Director, Regulatory Affairs
Mcra LLC
803 7th Street NW
Washington, District of Columbia 20001

Re: K221047
Trade/Device Name: SILO TFX MIS Sacroiliac Joint Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR
Dated: August 31, 2022
Received: August 31, 2022

Dear Mr. Pollard:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*

K221047

Device Name

SILO TFX MIS Sacroiliac Joint Fixation System

Indications for Use *(Describe)*

The Aurora Spine SILO TFX MIS Sacroiliac Joint Fixation System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"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:** SILO TFX MIS Sacroiliac Joint Fixation System

**Manufacturer:**
Aurora Spine, Inc.
1930 Palomar Point Way, Suite #103,
Carlsbad, CA 92008, USA

**Contact:**
Laszlo Garamszegi
CTO/ Co-Founder
1930 Palomar Point Way, Suite #103
Carlsbad, CA 92008, USA
Phone: 760.424.2004
Email: lgaramszegi@auroraspine.us

**Prepared by:**
Samuel Pollard
Director, Regulator Affairs
MCRA, LLC
803 7th Street NW, Floor 3
Washington, DC 20001
Email: spollard@mcra.com

**Date Prepared:** April 8, 2022

**Classifications:** 21 CFR §888.3040

**Classification Name:** Smooth Or Threaded Metallic Bone Fixation Fastener

**Common Name:** Sacroiliac Joint Fixation

**Class:** II

**Product Codes:** OUR

**Indications for Use:**
The Aurora Spine SILO TFX MIS Sacroiliac Joint Fixation System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

**Device Description:**
The Aurora Spine SILO TFX MIS Sacroiliac Joint Fixation System includes the SILO TFX Cone, SILO TFX Screw, and the SILO TFX Locking Screw and associated manual surgical instruments. The SILO TFX Cone is comprised of titanium alloy and incorporates a hollow conical shaped barrel with two openings for bone screws for additional anchoring. During the procedure, the implant is inserted in line with the SI Joint via a posterior surgical

approach, and bone graft material is placed in the barrel of the implant to facilitate additional bone incorporation after surgery.

**Primary Predicate Device:**
The Aurora Spine SILO TFX MIS Sacroiliac Joint Fixation System is substantially equivalent to the Rialto™ SI Fusion System, with regard to indications and design.

**Table 7-1: Primary Predicate Devices**

| Device Name(s) | Manufacturer | K-Number |
|---|---|---|
| Rialto™ SI Fusion System | Medtronic | K161210 |

**Secondary Predicate Devices:**
The Aurora Spine SILO TFX MIS Sacroiliac Joint Fixation System is substantially equivalent to the Catamaran Sacroiliac Joint Fixation System (CAT SIJ Fixation System), and the SImmetry® Sacroiliac Joint Fusion System, with regard to indications and design.

**Table 7-2: Secondary Predicate Devices**

| Device Name(s) | Manufacturer | K-Number |
|---|---|---|
| Catamaran Sacroiliac Joint Fixation System (CAT SIJ Fixation System) | Tenon Medical, Inc. | K180818 |
| SImmetry® Sacroiliac Joint Fusion System | Zyga Technology, Incorporated | K151818 |

**Performance Testing Summary:**
The subject device underwent static and dynamic axial compression and static and dynamic compressive shear testing per ASTM 2077, as well as static and dynamic vertical shear testing. The subject devices met all acceptance criteria for all tests. A side-by-side cadaver study was performed to support the performance of the device. The range of motion of the SILO TFX System was compared to a legally marketed predicate device. The results of the cadaver study demonstrated that the SILO TFX System provides comparable stability of the joint to the predicate.

**Comparison of Technological Characteristics:**
The subject device was demonstrated to be substantially equivalent to the predicate cited in the passage above with respect to indications, design, materials, function, manufacturing, and performance.

**Conclusion:**
The SILO TFX MIS Sacroiliac Joint Fixation System are substantially equivalent to the cited predicate devices with respect to indications for use, design, function, materials, and performance.