March 24, 2025

Aurora Spine
% Jeremi Leasure
Representative / Consultant
Medical Device Development
2390 Mission St Suite 8
San Francisco, California 94110

Re: K243865
Trade/Device Name: AERO MIS Facet Fusion System
Regulatory Class: Unclassified
Product Code: MRW
Dated: December 16, 2024
Received: December 17, 2024

Dear Jeremi Leasure:

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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K243865

Device Name

AERO MIS Facet Fusion System

Indications for Use *(Describe)*

The AERO MIS Facet Fusion System is indicated for the posterior surgical treatment at C2-S1 (inclusive) spinal levels for the
following:
- Spondylolisthesis,
- Spondylolysis,
- Pseudoarthrosis or failed previous fusions which are symptomatic, or
- 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.

The system is intended for use with bone graft material.

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.**

## 7. 510(k) Summary

| | |
|---|---|
| **Device Trade Name** | AERO MIS Facet Fusion System |
| **Manufacturer** | Aurora Spine Inc<br>1930 Palomar Point Way, Ste 103<br>Carlsbad CA 92008 |
| **Manufacturer Contact** | Laszlo Garamszegi<br>Chief Technology Officer |
| **Prepared by** | Jeremi M Leasure<br>Principal<br>Medical Device Development<br>2390 Mission St Ste 8<br>San Francisco CA 94110<br>(510) 424-4606<br>jeremileasure@mdevdev.com |
| **Date Prepared** | 16 December 2024 |
| **Regulation** | Unclassified |
| **Class** | Unclassified |
| **Product Codes** | MRW |

### Indications for Use

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The system is intended for use with bone graft material.

### Device Description

The AERO MIS Facet Fusion System contains various sized facet screws for bilateral stabilization of the facet joints from levels C2 through S1, inclusive. The system is supplied with various orthopedic instruments. There are various facet screw sizes available for implanting to accommodate a range of facet joint sizes and geometries.

**Primary Predicate Device**

The Aurora AERO MIS Facet Fusion System is substantially equivalent to the Ion Facet Screw System, regarding indications and design.

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

| Device Name(s) | Manufacturer | K-Number |
|---|---|---|
| Ion Facet Screw System | SurGenTec | K211855 |

**Performance Testing Summary**

The following non-clinical performance data were provided to demonstrate substantial equivalence of the subject device to the predicates.

- Static cantilever bending per ASTM F2193 and static pushout per ASTM F543.
- Sterilization and reprocessing validation per ISO 17665-1.
- Biocompatibility evaluation per ISO 10993-1.

**Comparison of Technological Characteristics**

The subject AERO MIS Facet Fusion System is substantially equivalent to the predicate Ion Facet Screw System previously cleared in 510k K211855. The device is contained in a device tray containing the required components to action the device, not provided sterile but can be sterilized via steam sterilization prior to use and are intended for posterior surgical treatment of the facet. All characteristics and indications between the AERO MIS Facet Fusion System and the predicates are similar, therefore the subject device is substantially equivalent to the predicate devices.

**Conclusion**

The Aurora AERO MIS Facet Fusion System is substantially equivalent to the cited predicate device with respect to indications for use, design, function, materials, and performance.