July 8, 2022

Aurora Spine, Inc.
% Justin Eggleton
VP, Spine Regulatory Affairs
Mcra LLC
803 7th Street NW
Washington DC, District of Columbia 20001

Re: K221399
Trade/Device Name: ZIP™ MIS Interspinous Fusion System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: May 12, 2022
Received: May 13, 2022

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 (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)*
K221399

Device Name
ZIP™ MIS Interspinous Fusion System

Indications for Use *(Describe)*
The Aurora Spine ZIP™ MIS Interspinous Fusion System is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to the spinous process for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), lumbar spinal stenosis, spondylolisthesis, trauma (i.e., fracture or dislocation), and/or tumor. The Aurora Spine ZIP™ MIS Interspinous Fusion System is intended for use with bone graft material and is not intended for stand-alone use.

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.***

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# 510(k) Summary

**Contact:** Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Phone: 202.552.5800
Email: jeggleton@mcra.com

**Date Prepared:** July 7, 2022

**Device Trade Name:** ZIP™ MIS Interspinous Fusion System

**Manufacturer:** Aurora Spine, Inc.
1920 Palomar Point Way
Carlsbad, CA 92008

**Common Name:** Interspinous Fusion Device

**Classification:** 21 CFR §888.3050; Spinal interlaminal fixation orthosis

**Class:** II

**Product Code:** PEK

**Reason for 510(k) Submission:**
The purpose of this 510(k) is to update the indications for use to the Aurora Spine ZIP™ MIS Interspinous Fusion System to include lumbar spinal stenosis.

**Indications For Use:**
The Aurora Spine ZIP™ MIS Interspinous Fusion System is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to the spinous process for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), lumbar spinal stenosis, spondylolisthesis, trauma (i.e., fracture or dislocation), and/or tumor. The Aurora Spine ZIP™ MIS Interspinous Fusion System is intended for use with bone graft material and is not intended for stand-alone use.

**Device Description:**
The Aurora Spine ZIP™ MIS Interspinous Fusion System is a bilateral locking plate system which attaches to the posterior noncervical spine at the spinous processes. The implants have superior and inferior surfaces and a central chamber for receiving bone graft. The devices are available in a variety of cylinders to accommodate variations in pathology and patient anatomy. The Aurora

Spine ZIP™ MIS Interspinous Fusion System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral spine.

**Primary Predicate Device:**
The Aurora Spine ZIP™ MIS Interspinous Fusion System with modified indications is substantially equivalent to the predicate Aurora Spine ZIP™ MIS Interspinous Fusion System (K141317, K140715, K133091) with respect to intended use, design, function, performance and materials.

**Additional Predicate Device:**
The Aurora ZIP™ MIS Interspinous Fusion System is substantially equivalent to the InSpan ScrewLES Fusion System (K213266) with respect to intended use, design, function, performance, materials, and indications for use.

**Technological Characteristics:**
The Aurora Spine ZIP™ MIS Interspinous Fusion System with modified indications has the same technological characteristics (i.e., design, material, manufacturing process) compared to the predicate Aurora Spine ZIP™ MIS Interspinous Fusion System (K141317, K140715, K133091) since the design has not changed in this submission. The Aurora Spine ZIP™ MIS Interspinous Fusion System has a similar design to the InSpan ScrewLES device with minor differences in dimensions. Both devices have spiked compression plates connected by a central bar.

**Clinical Performance Testing Summary:**
A literature review of was performed to support the expanded indications.

**Substantial Equivalence:**
Clinical and engineering rationales were provided as justification for substantial equivalence of the ZIP™ MIS systems to the previously cleared ZIP MIS Systems and InSpan ScrewLES Fusion System.

**Conclusion:**
The subject device is substantially equivalent to the predicate devices with respect to indications for use, design, function, materials, and performance.