May 27, 2022

Aurora Spine Inc
% Lucie Dalet
Senior Regulatory Consultant
RQM+
2251 San Diego Avenue, Suite B-257
San Diego, California 92110

Re: K220610
Trade/Device Name: SOLO-L
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: February 8, 2022
Received: March 3, 2022

Dear Lucie Dalet:

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
Brent Showalter, Ph.D.
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)*
K220610

Device Name
SOLO-L

Indications for Use *(Describe)*
SOLO-L is indicated for intervertebral body fusion of the spine in skeletally mature patients who have had at least six months of non-operative treatment. The device system is designed for use with allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and/or autograft to facilitate fusion. One device is used per intervertebral body space.

SOLO-L is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

SOLO-L 2-screw cages may be used as a standalone device only when two vertebral body bone screws are used. SOLO-L 4-screw cages may be used as a standalone device only when at least two vertebral body bone screws are inserted in the two medial fixation holes with one inferior and one superior screw trajectory. If the physician chooses to use SOLO-L anterior cages with fewer than two screws in the two medial fixation holes with one inferior and one superior screw trajectory, then an additional supplemental spinal fixation system cleared for use in the lumbosacral spine must be used.

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.

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510(k) Summary

DATE PREPARED
May 5, 2022

MANUFACTURER AND 510(k) OWNER
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DEVICE INFORMATION

Proprietary Name/Trade Name:	SOLO-L
Common Name:	Intervertebral Fusion Device With Integrated Fixation, Lumbar
Regulation Number:	21 CFR 888.3080
Class:	II
Product Code:	OVD
Premarket Review:	OHT6/Spinal Devices (DHT6B)
Review Panel:	Orthopedic

PREDICATE DEVICE IDENTIFICATION
The SOLO-L is substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K201671	A-Link Z / Acuity Surgical Devices, LLC	✓

The predicate device has not been subject to a design related recall.

DEVICE DESCRIPTION
SOLO-L is an anterior lumbar interbody fusion device (ALIF) intended to improve stability of the spine while supporting fusion. The SOLO-L constructs are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1. The cages include a central graft window which may be packed with allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and/or autograft prior to implantation. Components are offered in

different shapes and sizes to meet the requirements of the individual patient anatomy. SOLO-L is made from titanium alloy (Ti-6Al-4V ELI). An optional interbody component composed of polyetheretherketone (PEEK) with tantalum markers is available for modular cages.

INDICATIONS FOR USE

SOLO-L is indicated for intervertebral body fusion of the spine in skeletally mature patients who have had at least six months of non-operative treatment. The device system is designed for use with allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and/or autograft to facilitate fusion. One device is used per intervertebral body space.

SOLO-L is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

SOLO-L 2-screw cages may be used as a standalone device only when two vertebral body bone screws are used. SOLO-L 4-screw cages may be used as a standalone device only when at least two vertebral body bone screws are inserted in the two medial fixation holes with one inferior and one superior screw trajectory. If the physician chooses to use SOLO-L anterior cages with fewer than two screws in the two medial fixation holes with one inferior and one superior screw trajectory, then an additional supplemental spinal fixation system cleared for use in the lumbosacral spine must be used.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Aurora Spine believes that the SOLO-L is substantially equivalent to the predicate device based on the information summarized here:

The subject device has identical intended use, design and dimensions and uses identical materials and manufacturing processes as the standalone anterior constructs cleared in K201671.

SUMMARY OF NON-CLINICAL TESTING

The subject device has identical technological characteristics as the standalone anterior constructs cleared in K201671, including design, dimensions, materials, and manufacturing processes. Therefore, no additional non-clinical testing was provided to demonstrate substantial equivalence.

SUMMARY OF CLINICAL TESTING

No clinical data were provided in order to demonstrate substantial equivalence.

CONCLUSION

Since the subject and predicate devices have the same intended use and similar indications, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate device. The similar indications for use and identical technological characteristics for the proposed SOLO-L are assessed to be substantially equivalent to the predicate device.