May 4, 2021

Acuity Surgical Devices, LLC
℅ Lucie Dalet, Ph.D.
Senior Regulatory Specialist
Acknowledge Regulatory Strategies, LLC
2251 San Diego Ave, Suite B-257
San Diego, California 92110

Re: K201671
Trade/Device Name: A-Link Z
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: March 31, 2021
Received: April 2, 2021

Dear Dr. 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,

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)*
K201671

Device Name
A-Link Z

Indications for Use *(Describe)*
A-Link Z anterior cages are 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 systems are 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. A-Link Z anterior cages are 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. A-Link Z 2-screw anterior cages may be used as a stand alone device only when two (2) vertebral body bone screws are used. A-Link Z 4-screw anterior cages may be used as a stand alone device only when at least two (2) 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 A-Link Z anterior cages with fewer than two (2) 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.

A-Link Z anterolateral cages are 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 systems are 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. A-Link Z anterolateral cages are 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. A-Link Z anterolateral cages are intended to be used with supplemental spinal fixation system cleared for use in the lumbosacral spine.

A-Link Z lateral cages are 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 systems are 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. A-Link Z lateral cages are 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. A-Link Z lateral cages are intended to be used with supplemental spinal fixation system cleared for use in the lumbosacral spine.

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
March 31, 2021

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DEVICE INFORMATION

Proprietary Name/Trade Name:	A-Link Z
Regulation Description:	Intervertebral body fusion device
Regulation Number:	21 CFR 888.3080
Class:	Class II
Product Codes:	OVD, MAX
Premarket Review:	Orthopedic Devices (OHT6)/Spinal Devices (DHT6B)
Review Panel:	Orthopedic

PREDICATE DEVICE IDENTIFICATION
The A-Link Z is substantially equivalent to the following predicates:

	Primary Predicate Device		Additional Predicate Devices	
	K#	**Name of the device / Manufacturer**	**K#**	**Name of the device / Manufacturer**
A-Link Z Anterior Cages (Modular, Unitary, Open and FRA)	K133827	A-Link Z OsteoVasive, LLC	K083475	Lucent Magnum+ Spinal Elements, Inc.
			K191391	HEDRON™ Lumbar Spacers Globus Medical Inc.
A-Link Z Anterolateral Cages	K133827	A-Link Z OsteoVasive, LLC	K162212	Divergence-L Anterior/Oblique Lumbar Fusion System Medtronic Sofamor Danek USA, Inc.

	Primary Predicate Device		Additional Predicate Devices	
	K#	**Name of the device / Manufacturer**	**K#**	**Name of the device / Manufacturer**
A-Link Z Lateral Cages	K133827	A-Link Z OsteoVasive, LLC	K172816	TiGer Shark System Choice Spine, LP

The predicate devices have not been subject to a design related recall.

DEVICE DESCRIPTION

A-Link Z consists of six models of intervertebral body fusion devices intended for anterior, anterolateral, or lateral lumbar interbody fusion. The A-Link Z Modular Cages, A-Link Z Standard Cages, A-Link Z FRA Cages, and A-Link Z Open Cages are intended for anterior approach. A-Link Z AL Cages are intended for anterolateral approach. A-Link Z Lateral Cages are intended for lateral approach. The devices are intended to improve stability of the spine while supporting fusion. The A-Link Z constructs are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1. Components are offered in different shapes and sizes to meet the requirements of the individual patient anatomy. A-Link Z devices are made from titanium alloy (Ti-6Al-4V ELI) per ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications* and ASTM F3001 *Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI 5Extra Low Interstitial) with Powder Bed Fusion*, and an optional interbody component composed of polyetheretherketone (PEEK) per ASTM F2026 *Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications with tantalum markers* per ASTM F560 *Standard Specification for Unalloyed Tantalum for Surgical Implant Applications*.

INDICATIONS FOR USE

A-Link Z anterior cages are 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 systems are 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. A-Link Z anterior cages are 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. A-Link Z 2-screw anterior cages may be used as a stand alone device only when two (2) vertebral body bone screws are used. A-Link Z 4-screw anterior cages may be used as a stand alone device only when at least two (2) 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 A-Link Z anterior cages with fewer than two (2) 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.

A-Link Z anterolateral cages are 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 systems are 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. A-Link Z anterolateral cages are 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. A-Link Z anterolateral cages are intended to be used with supplemental spinal fixation system cleared for use in the lumbosacral spine.

A-Link Z lateral cages are 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 systems are 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. A-Link Z lateral cages are 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. A-Link Z lateral cages are intended to be used with supplemental spinal fixation system cleared for use in the lumbosacral spine.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Acuity Surgical Devices believes that the A-Link Z devices are substantially equivalent to the predicate devices based on the information summarized here:

The A-Link Z anterior cages have the same intended use and surgical approach as the devices cleared in K133827, K083475, and K191391. The subject devices have similar design and materials as the devices cleared in K133827. When compared to the primary predicate device, the main differences are the extended range of cage configurations and available sizes, the number of screws required for the construct to be considered as a standalone device, and the sterilization method. The dimensions of the subject devices are similar to the devices cleared in K083475 and K191391. The anterior constructs may be used as standalone devices when at least two (2) vertebral body bone screws are inserted in the two medial fixation holes with one inferior and one superior screw trajectory. While this standalone indication differs from the predicate device, it is equivalent to the standalone use of the predicate device cleared in K083475.

The A-Link Z antero-lateral cages have the same intended use and similar design, dimensions, and materials as the devices cleared in K133827 and K162212. When compared to the primary predicate device, the main differences are the surgical approach and the sterilization method. While the primary predicate device is indicated for anterior surgical approach, the A-Link Z antero-lateral cages are intended to be used in antero-lateral approach, similar to the predicate cleared in K162212.

The A-Link Z lateral cages have the same intended use and similar materials as the primary

predicate devices cleared in K133827. When compared to the primary predicate device, the main differences are the design, the surgical approach, and the sterilization method. While the primary predicate devices are designed and intended for anterior surgical approach, the A-Link Z lateral cages are designed and intended to be used in lateral approach, similar to the predicate device cleared in K172816.

In order to ensure that the different technological characteristics do not affect the safety and effectiveness of the subject device, mechanical testing and a worst-case analysis were conducted on the new implant sizes and configurations, and the sterilization method and packaging of the subject device were validated. Based on the testing conducted, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate devices.

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the A-Link Z. The following tests were performed to demonstrate safety based on current industry standards:

- Biocompatibility testing:

The subject device was subjected to biocompatibility testing in compliance to ISO 10993-1 *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*, ISO 10993-5 *Biological evaluation of medical devices — Part 5: Tests for In Vitro cytotoxicity* and ISO 10993-11 *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*.

- Performance testing:
    - Static and dynamic compression and compression shear (per ASTM F2077)
    - Subsidence (per ASTM F2267)

The results of these tests indicate that the A-Link Z is substantially equivalent to the predicate devices.

SUMMARY OF CLINICAL TESTING

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

CONCLUSION

Based on the testing conducted, including mechanical performance testing, design validation analysis, biocompatibility testing, and sterilization and packaging validation, it can be concluded that the subject device is substantially equivalent to the predicate devices and does not raise new issues of safety or effectiveness compared to the predicate devices.