July 22, 2022

Acuity Surgical Devices, LLC
Charlie Forton
Director of Engineering and Regulatory Affairs
8710 N. Royal Lane
Irving, Texas 75063

Re: K221535
Trade/Device Name: Align Lumbar Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: May 26, 2022
Received: May 27, 2022

Dear Charlie Forton:

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)*

K221535

Device Name
Align Lumbar Interbody Fusion System

Indications for Use *(Describe)*

The Align Lumbar Interbody Fusion System 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 systems are designed for use with allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and/or autograft to facilitate fusion.

The Align Lumbar Interbody Fusion System 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.

The Align Lumbar Interbody Fusion System is 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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SECTION 5: 510(k) SUMMARY

5.1 SUBMITTER

Acuity Surgical Devices LLC
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Date Prepared: 05/19/2022

5.2 DEVICE

Trade Name: Align Lumbar Interbody Fusion System

Common or Usual Name: Intervertebral body fusion device

Classification Name: Intervertebral fusion device with bone graft, lumbar

Regulation: 21 CFR 888.3080

Regulatory Class: II

Product Code: MAX

5.3 PREDICATE DEVICE

Predicate Device:	Aurora Spine Interbody Fusion System (K133967)
Additional Predicate Devices:	A-Link Z (K201671) TxTiHA IBF System & AxTiHA Stand-Alone ALIF System (K201614)

Subject Device	Primary Predicate	Additional Predicate Devices	
Align Lumbar Anterior Cages	Aurora Spine Interbody Fusion System, K133967	A-Link Z, K201671	TxTiHA IBF System & AxTiHA Stand-Alone ALIF System, K201614
Align Lumbar Anterolateral Cage	Aurora Spine Interbody Fusion System, K133967	A-Link Z, K201671	
Align Lumbar Lateral	Aurora Spine Interbody Fusion System, K133967	A-Link Z, K201671	
Align Lumbar Posterior Cage	Aurora Spine Interbody Fusion System, K133967		
Align Lumbar Transforaminal and Oblique Transforaminal Cage	Aurora Spine Interbody Fusion System, K133967	TxTiHA IBF System & AxTiHA Stand-Alone ALIF System, K201614	

5.4 DEVICE DESCRIPTION

The Align Lumbar Interbody Fusion System consists of several models of intervertebral body fusion devices. The Align ALIF unitary cages and Align fully round ALIF (FRA) cages are intended for anterior approaches. The Align AOLIF cages are intended for anterolateral approaches. The Align Lateral cages are intended for lateral approaches. The Align TLIF cages and Align Oblique TLIF cages are intended for transforaminal approaches. The Align PLIF cages are intended for posterior approaches.

Align Lumbar Interbody Fusion System devices are made from titanium alloy (Ti-6Al-4V ELI) per ASTM F3001 *Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion*. Align Lumbar Interbody Fusion System devices are also made from polyetheretherketone (Zeniva ZA-500 PEEK®) per ASTM F2026 *Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications*. The PEEK devices contain radiopaque markers constructed from Tantalum per ASTM F560 *Standard Specification for Unalloyed Tantalum for Surgical Implant Applications* to assist with intraoperative placement. The radiopaque markers are positioned so the implant can be visualized from an Anterior-Posterior (AP) and Lateral x-ray view.

Reusable instruments to support implantation of the subject device are provided with non-sterile implants in sterilization trays. Implants are also available sterile packaged.

5.5 INDICATIONS FOR USE

The Align Lumbar Interbody Fusion System 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 consisting of cancellous and/or corticocancellous bone graft and/or autograft to facilitate fusion.

The Align Lumbar Interbody Fusion System 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.

The Align Lumbar Interbody Fusion System cages are intended to be used with supplemental spinal fixation system cleared for use in the lumbosacral spine.

5.6 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Acuity Surgical Devices LLC believes that the Align Lumbar Interbody Fusion System is substantially equivalent to the predicate and reference devices based on information summarized here:

For the Align Lumbar Interbody Fusion System, all devices have similar indications for use as the devices cleared in **K133967, K201671,** and **K201614**.

The Align Lumbar anterior cages have a similar surgical approach as the devices cleared in **K133967, K201671,** and **K201614**. The device's function, type of bone graft, need for supplemental fixation, and sterilization methods of the subject device and primary predicate are the same. The subject devices have the same design materials as the devices cleared in **K201671**. When compared to the primary predicate device, the main differences are the extended range of cage configurations and available sizes. The dimensions of the subject devices are similar to the devices cleared in **K133967, K201671,** and **K201614**.

The Align Lumbar anterolateral cages have a similar surgical approach as the devices cleared in **K133967** and **K201671**. The subject device has the same implant shape with graft window and threaded instrument attachment and uses the same sterilization methods as the devices cleared in **K133967** and **K201671**. The design material and implantation anatomical site is the same for the subject device and the device cleared in **K201671**. When compared to the predicate and reference devices, the main differences are the extended range of dimensions and size offerings.

The Align Lumbar lateral cages have a similar surgical approach as the devices cleared in **K133967** and **K201671**. The subject devices have the same design materials as the devices cleared in **K201671**. The subject device has the same implant shape with graft window and threaded instrument attachment and uses the same sterilization methods as the devices cleared in **K133967** and **K201671**. The main differences are the extended range of cage configurations and size offerings when compared to the predicate and reference devices. The dimensions of the subject devices are similar to the devices cleared in **K133967** and **K201671**.

The Align Lumbar transforaminal and oblique transforaminal cages have the same function, implant shape and design with graft window and threaded instrument attachment, requirement for supplement fixation, and sterilization methods as the devices cleared in **K133967.** The design material is similar for the subject device and primary predicate device. The subject device has an extended range of cage configurations and available sizes compared to the primary predicate device, **K133967**.

The Align Lumbar posterior cages have the same function, implant shape and design with graft window and threaded instrument attachment, requirement for supplement fixation, and sterilization methods as the devices cleared in **K133967** and **K201614.** The design material is similar for the subject device and primary predicate device. The subject device has an extended range of cage configurations and available sizes compared to the devices cleared in **K133967** and **K201614**.

In order to ensure that the different technological characteristics do not affect the safety and effectiveness of the subject device, both mechanical testing and worst-case analysis were conducted on new implant sizes and configurations. The sterilization method and packaging of the subject device were validated and remain unchanged. 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 device.

5.7 SUMMARY OF NON-CLINICAL TESTING

The following performance data were provided in support of the substantial equivalence determination.

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.*

Bench Testing

The subject device underwent verification evaluation (static compression, dynamic compression, static compression-shear, dynamic compression-shear per ASTM F2077 *Test Methods For Intervertebral Body Fusion Devices*, and subsidence testing per ASTM F2267 *Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression*) to ensure that the design features met the required mechanical strength criteria for their intended use.

Performance equivalence was shown through the verification comparison to the predicate device.

The results on the non-clinical testing demonstrated that the subject device met the acceptance criteria of the standard and is substantially equivalent to the predicate devices.

5.8 CLINICAL TESTING

No clinical data was provided to demonstrate substantial equivalence.

5.9 CONCLUSIONS

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 does not raise new issues of safety or effectiveness compared to the predicate devices.