July 17, 2024

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

Re: K241413
Trade/Device Name: sagAlign Lumbar Cage System (Various PNs)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: May 17, 2024
Received: May 17, 2024

Dear Chuck 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 (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.

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,

Aakash Jain -S

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241413

Device Name

sagAlign Lumbar Cage System (Various PNs)

Indications for Use *(Describe)*

The sagAlign Lumbar Cage System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s).

sagAlign Lumbar Cage implants are to be used with allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and/or autograft and implanted via an open posterior approach. sagAlign Lumbar Cage implant is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

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.

510(k) Summary

Prepared on: 2024-07-11

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Acuity Surgical Devices LLC
Applicant Address	8710 N. Royal Lane Irving TX 75063 United States
Applicant Contact Telephone	512-585-3537
Applicant Contact	Mr. Chuck Forton
Applicant Contact Email	cforton@acuitysurgical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	sagAlign Lumbar Cage System (Various PNs)
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral Fusion Device With Bone Graft, Lumbar
Regulation Number	888.3080
Product Code(s)	MAX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K080537	L-Varlock Lumbar Cages	MAX
K222561	Align	MAX
K221535	Align Lumbar Interbody Fusion System	MAX

Device Description Summary

21 CFR 807.92(a)(4)

The sagAlign Lumbar Cage System is an interbody expandable lumbar cage. It is implanted by a posterior approach and supplemented by posterior fixation which is required to achieve fusion. The lumbar cages can be gradually expanded to reach the specific angle chosen by the surgeon, allowing restoration of disc height and the ideal lordosis.
The sagAlign Lumbar Cages are delivered non-sterile or sterile packaged. The cages are available in several sizes in different heights, widths, and lengths. One or two cages may be implanted for each treated level. The sagAlign Lumbar Cages will be composed of titanium alloy and may have a surface treatment coating of Promimic HAnano Surface (hydroxyapatite (HA) coating). The Promimic HAnano Surface coated cages are only available sterile.
Reusable instruments to support implantation of the subject device are provided with non-sterile implants in sterilization trays.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The sagAlign Lumbar Cage System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two
contiguous levels from L2-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s).

sagAlign Lumbar Cage implants are to be used with allogenic bone graft comprised of cancellous and/or corticocancellous bone graft

and/or autograft and implanted via an open posterior approach. sagAlign Lumbar Cage implant is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The sagAlign Lumbar Cage System has the similar indications for use as the devices cleared in K080537, K222561, and K221535. The difference in indications for use between the subject device and the primary predicate device (K080537) is the description of the bone graft material.

Technological Comparison 21 CFR 807.92(a)(6)

Acuity Surgical Devices LLC believes that the sagAlign Lumbar Cage System is substantially equivalent to the primary predicate and additional predicate devices based on information summarized here:

For the sagAlign Lumbar Cage System, all devices have similar indications for use as the devices cleared in K080537.

The sagAlign Lumbar Cage System has the same surgical approach, implanted via an open posterior surgical approach in the lumbar spine at one or two contiguous levels from L2-S1, as the primary predicate device cleared in K080537. Both the subject device and primary predicate (K080537) also require supplement fixation. The subject device, sagAlign Lumbar Cage System, has a similar design, rectangular shape, and dimensions as the primary predicate device (K080537) and additional predicate devices (K222561 and K221535). The subject device is the same design as the primary predicate device (K080537) with expanded range of sizes. The subject device and primary predicate device (K080537) have the same expansion mechanism and instrument attachment. The subject device has graft windows and same ridges / teeth to resist migration and increase surface contact as the primary predicate device cleared in K080537. The subject device and primary predicate devices (K080537) implants are both made of the same material, titanium alloy per ASTM F136/ISO 5832-2, except the subject device's implants may have an optional coating. The optional implant coating for the subject device and additional predicate device (K222561) are the same material, hydroxapatite coating (Promimic HAnano Surface). The subject device and additional predicate devices (K222561 and K221535) may be sterilized using either gamma or steam sterilization.

In order to ensure that the different technological characteristics do not affect the safety and effectiveness of the subject device, a performance evaluation was performed to demonstrate that the mechanical strength and fatigue endurance of the sagAlign Lumbar Cage is comparable to the primary predicate and additional predicate devices.

The sagAlign Lumbar Cage System is substantially equivalent to and is as safe and as effective as, the legally marketed predicate device, L-Varlock Lumbar Cages (K080537) under regulation 21CFR 888,3080, product code MAX.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

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.

It was verified that the new modifications of the subject device were demonstrated not to be worst-case compared to the predicate device.

The results on the non-clinical testing demonstrated that the subject device is substantially equivalent to the predicate devices.

Based on the results of mechanical testing conducted on the worst-case devices according to FDA Class II Special Controls Guidance, the subject device is considered substantially equivalent to the predicate devices cleared in K080537 and does not raise new issues of safety or effectiveness compared to the predicate device.