April 22, 2025

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

Re: K243386
Trade/Device Name: Ventris IBFD
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: March 21, 2025
Received: March 21, 2025

Dear Mr. 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Brent Showalter -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243386

Device Name

Ventris (Various PNs)

Indications for Use *(Describe)*

Ventris 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. Ventris 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.

Ventris 2-screw anterior cages may be used as a stand alone device only when two (2) vertebral body bone screws are used. Ventris 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 Ventris 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. Ventris anterior cages are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, in patients having an ODI >40 and diagnosed with severe symptomatic adult spinal deformity (ASD) conditions. When used to treat ASD, or when cages with more than 20° of lordosis are used, Ventris anterior cages must be used with a supplemental spinal fixation system cleared for use in the lumbosacral spine and cannot be used as a stand alone.

Ventris 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. Ventris anterolateral cages are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, in patients having an ODI >40 and diagnosed with severe symptomatic adult spinal deformity (ASD) conditions. Ventris 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. Ventris anterolateral cages are intended to be used with a supplemental spinal fixation system cleared for use in the lumbosacral spine.

Ventris 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. Ventris lateral cages are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, in patients having an ODI >40 and diagnosed with severe symptomatic adult spinal deformity (ASD) conditions. Ventris 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. Ventris lateral cages are intended to be used with a 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) #: K243386

510(k) Summary

Prepared on: 2025-03-21

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	Ventris (Various PNs)
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral Fusion Device With Integrated Fixation, Lumbar
Regulation Number	888.3080
Product Code(s)	OVD, MAX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K201671	A-Link Z	OVD
K222561	Align	OVD
K232282	aprevo® anterior and lateral lumbar interbody fusion device; aprev	MAX
K230894	NuVasive Modulus ALIF System	OVD
K223413	Osseus Fusion Systems Pisces-SA Standalone ALIF Interbody Sy	OVD

Device Description Summary

21 CFR 807.92(a)(4)

The Ventris system consists of intervertebral body fusion devices intended for lumbar interbody fusion using an anterior lumbar interbody fusion surgical approach (ALIF), anterolateral (i.e., oblique) lumbar interbody fusion surgical approach (AOLIF), or a lateral lumbar interbody fusion surgical approach (LLIF). The devices are intended to improve stability of the spine while supporting fusion. The Ventris constructs are intended for use at one or two contiguous levels in the lumbar spine (L2-S1). The components are offered in different shapes and sizes to meet the requirements of the individual patient's anatomy and are provided sterile.

Ventris cages are available in six configurations: Ventris Ti Interbody anterior four-hole constructs for ALIF approach, Ventris Ti FRA Interbody anterior fully round ALIF (FRA) constructs for ALIF approach, Ventris Ti Open Interbody anterior two-hole constructs for ALIF approach, Ventris TI AL Interbody anterolateral (i.e., oblique) constructs for OLIF approach, Ventris TI Lateral FX two-screw lateral constructs for LLIF approach, and Ventris TI Lateral Interbody lateral constructs for LLIF approach. All cages are also available in increased surface area options that provide additional endplate surface area. For the increased surface area cages, the outer footprint remains the same, but the volume of the internal graft window is reduced, creating more endplate surface area.

Ventris cages are secured on the vertebral bodies using bone screws. A cover plate assembly prevents the screws from backing out after insertion. The cages and cover plates are made of titanium alloy (Ti-6Al-4V ELI) per ASTM F3001 Standard Specification for Additive Manufacturing Titanium-6 Alulminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion. The bone screws and cover plate screws 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. All anterior and anterolateral constructs are zero profile, reducing potential for vessel interference with the anterior column.

All Ventris cages and cover plates are manufactured using the L-PBF (laser powder bed fusion) additive manufacturing method. L-PBF allows for the formation of solid, non-porous cages with a layered porous lattice structure on the surfaces of the components, including the surfaces of the interior graft window. This intricate structure facilitates bone in-growth by providing a larger surface of implant/bone contact than a buffed surface. Interbody cages and bone screws may also be titanium anodized to allow for identification of various heights/sizes by color.

Ventris Ti Interbody cages, Ventris Ti FRA Interbody cages, Ventris Ti Open Interbody cages, Ventris Ti AL Interbody cages, Ventris Ti Lateral FX Interbody cages, Ventris Ti Lateral Interbody cages, and Ventris bone screws are also available with a Promimic HAnano Surface (hydroxyapatite (HA) coating). Cages and bone screws are coated with a 20nm HA layer composed of crystalline hydroxyapatite particles that mimic human bone tissue through shape, composition, and structure. This surface treatment increases implant anchoring by facilitating osseointegration and enhancing early bone growth. All Ventris devices are only available sterile packaged.

Non-sterile, reusable surgical instruments to support implantation of the system are provided for use with Ventris devices are provided in steam sterilization trays.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

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

Ventris has similar indications for use as the devices cleared in K201671, K222561, K232282, K230894, and K223413 The difference in indications for use between the subject device and the primary predicate device (K201671) is the addition of indications for treatment of severe symptomatic adult spinal deformity (ASD) conditions, and the usage of cages with more than 20° of lordosis, with both new indications requiring the use of a supplemental spinal fixation system cleared for use in the lumbosacral spine.

Technological Comparison 21 CFR 807.92(a)(6)

The Ventris system has similar indications for use, design and dimensions, and uses identical materials as the devices cleared in primary predicate device K201671. The subject device also has identical or similar technological characteristics as the primary predicate device.

Differences in technological characteristics from the predicate devices include introduce a change in the device name, additional implant height and lordosis offerings, additional implant configurations with increased surface area options, additional bone screw and cover plate options, an update to instrument designs, and additional instrument options. Furthermore, the additive manufacturing process was changed to a new supplier.

The subject device has identical or similar technological characteristics as the reference predicate devices cleared in K222561, K230894, K232282, and K223413 with an extended range of implant sizes and lordosis. The subject device also has similar indications for use as the devices cleared in K230894, K232282, and K223413. The subject device comes with an optional HA coating, which is the same material as the device cleared in K222561.

In order to ensure that these technological characteristics do not affect the safety and effectiveness of the subject device, mechanical testing and a worst-case analysis was conducted on the new implant sizes and configurations. 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 K201671, K222561, K230894, K232282, and K223413.

The Ventris system is substantially equivalent to and is as safe and effective as the legally marketed predicate device, A-Link Z (K201671) under regulation 21 CFR 888.3080, product codes OVD and MAX.

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

The subject device underwent mechanical performance testing to validate that the performance of the worst-case subject device is substantially equivalent to the previously cleared predicate devices. Worst-case testing also took into account the effect of all process steps, including HIP and Non-HIP test articles. Test methods include static compression, static compression shear, dynamic compression, and 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 Devices Under Static Axial Compression. Mechanical testing ensured that the design features of the subject device met the required mechanical strength criteria for their intended use. Additional testing included tensile testing, microstructure assessment, and chemical composition assessment per ASTM F3001. The performance testing demonstrated substantial equivalence between the subject and predicate devices. The results of the non-clinical testing did not identify any new or increased risks associated with the change in additive manufacturing supplier. Performance equivalence demonstrated that the subject device met the acceptance criteria of the standards and is substantially equivalent to the predicate devices.

Ventris devices are substantially equivalent to the previously cleared devices with respect to their indications for use, design, function, and performance.