July 30, 2025

Acuity Surgical Devices LLC
Chuck Forton
VP of New Product Development
8710 N Royal Lane
Irving, Texas 75063

Re: K251735
Trade/Device Name: Stabilis SA Cervical Stand-Alone System (Various PNs)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: June 5, 2025
Received: June 6, 2025

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251735

Device Name
Stabilis SA Cervical Stand-Alone System (Various PNs)

Indications for Use *(Describe)*
The Stabilis SA Cervical Stand-Alone 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 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.

The Stabilis SA Cervical Stand-Alone System is intended for use at either one level or two contiguous levels in the cervical spine, from C2 to T1, 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.

Stabilis SA Cervical Stand-Alone System cages may be used as a stand-alone device when two (2) vertebral body bone screws are used. Stabilis SA Cervical Stand-Alone System cages with four (4) screw holes may be used as a stand-alone device when at least two (2) vertebral body bone screws are utilized with one inferior and one superior screw trajectory on opposite sides of the cage. If the physician chooses to use Stabilis SA Cervical Stand-Alone System cages with fewer than two (2) screws, then an additional supplemental spinal fixation system cleared for use in the cervical spine must be used.

Stabilis SA Cervical Stand-Alone System cages with four (4) screw holes may only be used at contiguous levels if at least two (2) vertebral body bone screws are utilized in each cage with one inferior and one superior screw trajectory on opposite sides of the cage, such that no more than two (2) vertebral body bone screws are implanted at the shared vertebral body with one inferior and one superior screw trajectory on opposite sides of the cages. Additionally, a cage with four (4) screw holes and a cage with two (2) screw holes can be implanted contiguously only if the cage with four (4) screw holes uses at least (2) vertebral body bone screws with one inferior screw on the left side of the cage and one superior screw on the right side of the 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

Contact Details

Applicant Name: Acuity Surgical Devices LLC
Applicant Address: 8710 N. Royal Lane
Irving TX, 75063 United States
Applicant Contact No.: (512) 585-3537
Applicant Contact: Mr. Chuck Forton
Applicant Contact email: cforton@acuitysurgical.com

Date Prepared: July 16, 2025

Device Name

Device Trade Name: Stabilis SA Cervical Stand-Alone System (Various PNs)
Common Name: Intervertebral body fusion device
Classification Name: Intervertebral Fusion Device With Integrated Fixation, Cervical
Regulation Number: 888.3080
Product Code(s): OVE, ODP

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K230639	ODP	Align Cervical Interbody Fusion Device	Acuity Surgical Devices LLC
Additional Predicate Devices			
K211417	OVE	F3D-C2 Cervical Stand-Alone System	CoreLink, LLC
K200543	OVE	NEXXT MATRIXX Stand Alone Cervical-Turn Lock (-TL) System	Nexxt Spine, LLC
K111272	ODP	Rhausler Plage Anterior Cervical Fusion System	Rhausler Inc

Device Description

The Stabilis SA cages are intervertebral body fusion devices intended for cervical interbody fusion using an anterior approach. The devices are intended to improve stability of the spine while supporting fusion. Stabilis SA constructs are intended for use at one or two contiguous levels in the cervical spine (C2-T1). The components are offered in different shapes and sizes to meet the requirements of the individual patient anatomy.

Stabilis SA Cervical Stand-Alone System cages are made of 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. All cages 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. The cages are also titanium anodized to allow for identification of various heights by color. The Stabilis SA Cervical Stand-Alone System cages are secured on the vertebral bodies using bone screws. The bone screws are machined 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 passivated according to ASTM F86 Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants.

Stabilis Ti SA 2 Interbody, Stabilis Ti SA 2 Interbody, Curved, Stabilis Ti SA 4 Interbody, Stabilis Ti SA 4 Interbody, Curved, Stabilis Ti ZP Interbody, Stabilis Ti ZP Interbody, Curved cages, and bone screws are also available with a hydroxyapatite coating to increase implant anchoring by facilitating osseointegration and enhancing early bone growth. All Stabilis SA Cervical Stand-Alone implants are only available sterile packaged.

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

Intended Use / Indications for Use

The Stabilis SA Cervical Stand-Alone 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 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.

The Stabilis SA Cervical Stand-Alone System is intended for use at either one level or two contiguous levels in the cervical spine, from C2 to T1, 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.

Stabilis SA Cervical Stand-Alone System cages may be used as a stand-alone device when two (2) vertebral body bone screws are used. Stabilis SA Cervical Stand-Alone System cages with four (4) screw holes may be used as a stand-alone device when at least two (2) vertebral body bone screws are utilized with one inferior and one superior screw trajectory on opposite sides of the cage. If the physician chooses to use Stabilis SA Cervical Stand-Alone System cages with fewer than two (2) screws, then an additional supplemental spinal fixation system cleared for use in the cervical spine must be used.

Stabilis SA Cervical Stand-Alone System cages with four (4) screw holes may only be used at contiguous levels if at least two (2) vertebral body bone screws are utilized in each cage with one inferior and one superior screw trajectory on opposite sides of the cage, such that no more than two (2) vertebral body bone screws are implanted at the shared vertebral body with one inferior and one superior screw trajectory on opposite sides of the cages. Additionally, a cage with four (4) screw holes and a cage with two (2) screw holes can be implanted contiguously only if the cage with four (4) screw holes uses at least (2) vertebral body bone screws with one inferior screw on the left side of the cage and one superior screw on the right side of the cage.

Indications for Use Comparison

The Stabilis SA Cervical Stand-Alone System has similar Indications for Use as the primary predicate device, Align Cervical Interbody Fusion System (K230639) and similar Indications for Use to the additional predicate devices cleared in K211417, K200543, and K111272. The subject device is indicated for the same patient population, condition, and mechanism of action as the additional predicate devices.

Technological Comparison

The Stabilis SA Cervical Stand-Alone System has similar indications, design, similar dimensions, and uses identical materials as the primary predicate device, K230639. The subject device also has identical or similar technological characteristics as the primary predicate device.

Differences between the subject device and primary predicate device include a change in the device name, new stand-alone cervical indications for use statements, additional implant configurations with integrated screw-based fixation, additional implant configurations with curved endplates, an update to instrument designs, and additional instrument options. The additive manufacturing process was also changed to a new supplier.

The subject device has identical or similar characteristics to additional predicate devices K211417, K200543, and K111272 with similar implant configurations with integrated screw-based fixation. The subject device comes with an optional HA coating, which is the same material as the primary predicate device cleared in K230639.

To ensure these technological characteristics do not affect the safety and effectiveness of the subject device, a worst-case analysis and resulting worst-case configuration mechanical testing 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 any new issues of safety and effectiveness as compared to the additional predicate devices K211417, K200543, and K111272.

The Stabilis SA Cervical Stand-Alone System is substantially equivalent to the legally marketed predicate device Align Cervical Interbody Fusion System (K230639) under regulation 21 CFR 888.3080, product codes OVE and ODP.

Non-Clinical and/or Clinical Tests Summary & Conclusions

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. Test methods including static axial compression, static axial compression shear, static torsion, dynamic axial compression, dynamic axial compression shear, and dynamic torsion per ASTM F2077 Test Methods for Intervertebral Body Fusion Devices, and static subsidence testing per ASTM F2267 Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Devices Under Static Axial Compression 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.

Clinical Testing was Not Applicable.

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.