July 10, 2026

SIGNUS Medinzintechnik GmbH
% Kara Johnson
Vice President of Regulatory Affairs
Kapstone Medical
520 Elliot Street
Charlotte, North Carolina 28202

Re: K261031
Trade/Device Name: POSEIDON® ST
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: June 11, 2026
Received: June 11, 2026

Dear Kara Johnson:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

KATHERINE D. KAVLOCK -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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261031

Please provide the device trade name(s).

POSEIDON ST

Please provide your Indications for Use below.

The POSEIDON ST is used to maintain disc space distraction and structural stability until fusion occurs in skeletally mature adults requiring thoracic/lumbar interbody replacement.

POSEIDON ST is indicated for use following complete or incomplete corpectomy due to destructive damage of the vertebral body, such as that caused by tumors, fractures, or osteomyelitis, in the thoracic and lumbar regions of the spine (TH1-L5). The access is posterior, lateral, anterolateral or anterior depending on the indication. The interior of the spacers can be packed with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate as an adjunct to fusion.

This device is intended to be used with FDA-cleared supplemental spinal fixation systems that have been labeled for use in the thoracic, and/or lumbar spine (i.e., posterior screw and rod systems, anterior plate systems, and anterior screw and rod systems). When used at more than two levels, supplemental fixation should include posterior fixation.

The device is intended for use in skeletally mature patients.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) Summary

Applicant Name and Address:	Kapstone Medical LLC 520 Elliot Street Charlotte, NC 28202 on behalf of Signus Medinzintechnick GmbH Industriestrasse 2 Alzenau, Germany 63755
Date Summary was Prepared:	March 27, 2026
Contact Person:	Kara Johnson Vice President of Regulatory Affairs Kapstone Medical 520 Elliot Street Charlotte, NC 28202 (704) 843-7852 kjohnson@kapstonemedical.com
Trade/Device Name:	POSEIDON® ST
Common Name:	Spinal Vertebral Body Replacement Device
Device Class:	Class II
Regulation Numbers:	888.3060
Classification Name and Product Codes:	Spinal intervertebral body fixation orthosis; MQP
Legally Marketed Predicate Device: **(Primary Predicate)**	Nuvasive X-Core Expandable VBR System (K142205)
(Reference Predicate)	SACRONAIL® Transsacral System (K212755)
(Reference Predicate)	DIPLOMAT® Spinal System (K151704)

Device Description:

POSEIDON ST is a vertebral body replacement (VBR) implant for use in the spine. It is used to restore the spinal column as a temporary placeholder until a solid bony fusion has taken place. For adaptation to different patient anatomies, the implants are available in various designs, footprints, heights, and angulations. For secure primary stabilization, the upper and lower surfaces are provided with "teeth" for resisting migration. The implants have cavities that can be filled with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft to promote bony incorporation. Bone graft is deposited around the implant. The devices are intended to be used with supplemental spinal fixation. The system also includes instrumentation intended to aid in the fit and placement of the implants.

The POSEIDONT ST implants include main bodies, endplates, connecting screws, and locking screws, which are sterilized via gamma irradiation and are thus provided sterile. The system instrumentation is provided non-sterile.

Indications for Use:

The POSEIDON ST is used to maintain disc space distraction and structural stability until fusion occurs in skeletally mature adults requiring thoracic/lumbar interbody replacement.

POSEIDON ST is indicated for use following complete or incomplete corpectomy due to destructive damage of the vertebral body, such as that caused by tumors, fractures, or inflammations in the thoracic and lumbar regions of the spine (TH1-L5). The access is posterior, lateral, anterolateral or anterior depending on the indication. The interior of the spacers can be packed with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate as an adjunct to fusion.

This device is intended to be used with FDA-cleared supplemental spinal fixation systems that have been labeled for use in the thoracic, and/or lumbar spine (i.e., posterior screw and rod systems, anterior plate systems, and anterior screw and rod systems). When used at more than two levels, supplemental fixation should include posterior fixation.

The device is intended for use in skeletally mature patients.

Technological Characteristics:

The POSEIDON ST is a modular system. The POSEIDONT ST implants, made of Titanium alloy, include main bodies, endplates, connecting screws, and locking screws, which are provided sterile. The main bodies come in both static and distractable versions. The endplates come in a variety of angles in both rectangular and round (with and without spikes) shapes. A main body is connected to two end plates of the desired size and angulation. If desired, an extension body can be added to the base

body to achieve additional vertical overall length. The distractable base body is secured at the desired height with the Locking screw. The Connecting screw connects the end plates to the main body. Implant placement is supported by reusable instrumentation that is designed to aid insertion and positioning.

Non-clinical Performance Evaluation:

The following confirmatory testing was conducted on the proposed POSEIDON ST system to verify that device performance is substantially equivalent to the predicate devices. Specifically, the following tests were conducted:

- Mechanical performance testing recommended by the FDA for the MQP produce code including:
  - Static Axial Compression per ASTM F2077-24
  - Static Axial Torsion per ASTM F2077-24
  - Dynamic Axial Compression per ASTM F2077-24
  - Dynamic Axial Torsion per ASTM F2077-24
  - Static Subsidence per ASTM F2267-2018
- Biocompatibility per ISO 10993
- Sterile Packaging Testing per ISO 11607
- Sterilization Validation per VDmax method
- Reprocessing/Cleaning Validation per ISO 17665
- Usability/Human Factors Validation

The assessment of the non-clinical data in this submission supports that the subject device is safe, effective, and performs as well as or better than the predicate device(s). No issues of safety or efficacy were raised.

Conclusion:

Based on a comparison of the intended use and technological characteristics to the predicate devices and on the results of confirmatory testing, it is concluded that the proposed POSEIDON ST system is substantially equivalent.