February 11, 2025

SIGNUS Medizintechnik GmbH
% Emily Szabo
Quality & Regulatory Engineer
JALEX Medical, LLC
27865 Clemens Road, Suite 3
Westlake, Ohio 44145

Re: K243188
Trade/Device Name: CYLOX® ST
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: September 30, 2024
Received: December 19, 2024

Dear Emily Szabo:

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,

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

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)*

K243188

Device Name

CYLOX® ST

Indications for Use *(Describe)*

The CYLOX® ST implants are interbody fusion devices intended for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies.

The cervical device is to be used in patients who have had at least six (6) weeks of non-operative treatment. The devices are to be used with autograft bone graft composed of cancellous, cortical, and / or corticocancellous bone and implanted via an anterior approach.

When used as a standalone system, CYLOX® ST is intended to be used as an adjunct to spinal fusion procedures at one level (C3-T1) and must be used with the CYLOX® ST bone screw fixation or connecting plate and must be secured with the corresponding locking screw.

When used with supplemental fixation, such as anterior cervical plates, CYLOX® ST is intended to be used as an adjunct to spinal fusion procedures at one or two levels of the cervical spine (C3-T1).

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

Applicant:	SIGNUS Medizintechnik GmbH Industriestrasse 2 D-63755 Alzenau, GERMANY
Date:	09/30/2024
Contact Person:	Emily Szabo, Ph.D.
Contact Telephone:	(216) 452-2658
Contact Fax:	(440) 933-7839
Device Trade Name:	**CYLOX® ST**
Common Name:	Intervertebral body fusion device;
Device Classification Name:	Intervertebral Fusion Device With Integrated Fixation, Cervical (21 CFR 888.3080)
Device Class:	II
Reviewing Panel:	Orthopedic
Product Code:	OVE, ODP
Primary Predicate Device:	**K201646 – Shoreline® ACS (Anterior Cervical System)**
Reference Device:	K241438 – SIGNUS TETRIS™ ST, TETRIS™ R ST

Device Description:
The SIGNUS CYLOX® ST Interbody System is an anterior cervical intervertebral body fusion system. The system is comprised of interbodies, plates, and screws. The interbody device can be used as a standalone implant with screw holes for integrated fixation, or as a construct fixed with a plate and screws. The interbody implants are additively manufactured from titanium alloy (Ti-6Al-4V ELI). The plates and screws are traditionally machined from titanium alloy (Ti-6Al-4V).

The SIGNUS CYLOX® ST Interbody System is placed in the C3 – T1 spinal region via the Cloward or Smith-Robinson approach. The interbody is available in four different footprints, with multiple heights and angulations. The standalone interbody contains a central hole and two holes angulated for fixation with screws into the cranial and caudal vertebral body. The construct interbody contains a central hole and indentation features to mate with the anterior plate.

The device is comprised of structural titanium in an open-pore grid structure. The large fenestration in the implant permits the cage to be packed with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

Indications for Use and Intended Use:
The CYLOX® ST implants are interbody fusion devices intended for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies.

The cervical device is to be used in patients who have had at least six (6) weeks of non-operative treatment. The devices are to be used with autograft bone graft composed of cancellous, cortical, and / or corticocancellous bone and implanted via an anterior approach.

When used as a standalone system, CYLOX® ST is intended to be used as an adjunct to spinal fusion procedures at one level (C3-T1) and must be used with the CYLOX® ST bone screw fixation or connecting plate and must be secured with the corresponding locking screw.

When used with supplemental fixation, such as anterior cervical plates, CYLOX® ST is intended to be used as an adjunct to spinal fusion procedures at one or two levels of the cervical spine (C3-T1).

Summary of Technological Characteristics:
The subject CYLOX® ST has the same intended use and indications for use as the predicate system. The technological characteristics of the subject system are similar to those of the predicate, and the information provided herein demonstrates that any differences do not impact safety or effectiveness.

Item	Subject Device	Primary Predicate	Equivalence
	SIGNUS CYLOX® ST	SeaSpine Shoreline®ACS (K201646)	
Classification Name	Intervertebral Fusion Device With Integrated Fixation, Cervical; Intervertebral Fusion Device With Bone Graft, Cervical	Intervertebral Fusion Device With Integrated Fixation, Cervical; Intervertebral Fusion Device With Bone Graft, Cervical	Substantially equivalent
Regulation	21 CFR 888.3080 (Intervertebral Body Fusion Device)	21 CFR 888.3080 (Intervertebral Body Fusion Device)	Substantially equivalent
Product Code	OVE, ODP	OVE, ODP	Substantially equivalent
Indications for Use	The CYLOX® ST implants are interbody fusion devices intended for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The cervical device is to be used in patients who have had at least six (6) weeks of non-operative treatment. The devices are to be used with autograft bone graft composed of cancellous, cortical, and / or corticocancellous bone and implanted via an anterior approach. When used as a standalone system, CYLOX® ST is intended to be used as an adjunct to spinal fusion procedures at one level (C3-T1) and must be used with the CYLOX® ST bone screw fixation or connecting plate and must be secured with the corresponding locking screw. When used with supplemental fixation, such as anterior cervical plates, CYLOX® ST is intended to be used as an adjunct to	The Shoreline ACS (Anterior Cervical System) are interbody fusion devices intended for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The Shoreline ACS implants are to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous, cortical, and / or corticocancellous bone and implanted via an anterior approach. The device is to be used in patients who have had at least six (6) weeks of non-operative treatment. When used as a standalone system, Shoreline ACS is intended to be used as an adjunct to spinal fusion procedures at one level (C2-T1) and must be used with the Shoreline ACS bone screw fixation and locking cover. When used with supplemental fixation, such as anterior cervical plates, the Shoreline Cervical low profile (TruProfile) Interbody	Substantially equivalent

Item	Subject Device	Primary Predicate	Equivalence
	SIGNUS CYLOX® ST	SeaSpine Shoreline®ACS (K201646)	
	spinal fusion procedures at one or two levels of the cervical spine (C3-T1).	Spacer is intended to be used as an adjunct to spinal fusion procedures at one or two levels of the cervical spine (C2-T1).	
Material	Cage: Ti-6Al-4V ELI per ASTM F3001 Plate: Ti-6Al-4V ELI per ASTM F136 Screws: Ti-6Al-4V ELI per ASTM F136	Cage: Polyetheretherketone (PEEK) per ASTM F2026, commercially pure titanium per ASTM F67 Plate: Ti-6Al-4V ELI per ASTM F136 Screws: Ti-6Al-4V ELI per ASTM F136	Substantially Equivalent
Manufacturing	Cages: additive manufacturing Plates: traditional machining Screws: traditional machining	Cages: Traditional molding and/or machining Plates: Traditional molding and/or machining Screws: Traditional molding and/or machining	Substantially Equivalent
Sterilization	Sterile	Sterile	Substantially Equivalent
Implantation Level	C3-T1	C2-T1	Substantially Equivalent

Performance Testing – Non-Clinical:
Substantial equivalence was supported by the results of verification testing to confirm that features, geometry and performance of the subject device performs as well as the predicate system, including:

- Static Axial Compression per ASTM F2077-22
- Static Axial Compression Shear per ASTM F2077-22
- Static Axial Torsion per ASTM F2077-22
- Dynamic Axial Compression per ASTM F2077-22
- Dynamic Axial Compression Shear per ASTM F2077-22
- Dynamic Axial Torsion per ASTM F2077-22
- Static Expulsion per ASTM F-04.25.02.02
- Static Subsidence per ASTM F2267-22

Performance Testing – Clinical:
Clinical testing was not applicable to support a substantial equivalence determination for the subject device.

Conclusion
Based on the indications for use, technological characteristics, and comparison with the predicate device, the subject device has demonstrated substantial equivalence.