September 11, 2024

SIGNUS Medizintechnik GmbH
℅ Chhavy Tep-Cullison
Regulatory Affairs Specialist
JALEX Medical, LLC
27865 Clemens Road, Suite 3
Westlake, Ohio 44145

Re: K241438
Trade/Device Name: Signus Tetris™ ST; Signus Tetris™ R ST
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: August 20, 2024
Received: August 20, 2024

Dear Chhavy Tep-Cullison:

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.

510(k) Number *(if known)*
K241438

Device Name
SIGNUS TETRIS™ ST;
SIGNUS TETRIS™ R ST

Indications for Use *(Describe)*
When used as an intervertebral fusion device, the TETRIS™ ST devices are intended for use at one level 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. The lumbar device is to be used in patients who have had six months of non-operative treatment. The devices are intended for use with a supplemental internal fixation system and with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Applicant: SIGNUS Medizintechnik GmbH
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D-63755 Alzenau, GERMANY

Date: 09/05/2024

Applicant Contact: Antje Schmidt, Regulatory Affairs Manager
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Regulation Number: 21 CFR 888.3080

Classification Product Code: MAX

Device Trade Name: **TETRIS™ ST, TETRIS™ R ST**
Common Name: Intervertebral body fusion device
Device Classification Name: Intervertebral fusion device with bone graft, lumbar
Device Class: II
Reviewing Panel: Orthopedic

Primary Predicate Device: **K122317 – SIGNUS TETRIS™ II**
Additional Predicates: K123758 – SIGNUS TASMIN® R
K141405 – SIGNUS MOBIS™ II ST

Device Description:
The SIGNUS TETRIS™ ST and SIGNUS TETRIS™ R ST system is an intervertebral fusion device to treat degenerative disc disease. The implants are additively manufactured from titanium alloy (Ti-6Al-4V). Each device is available in a single footprint, with multiple heights and angulations.

The SIGNUS TETRIS™ ST/ TETRIS™ R ST device is placed by a PLIF (Posterior Lumbar Interbody Fusion) approach in the L2 – S1 spinal region and should be inserted in pairs. 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.

Special 510(k) Submission – TETRIS™ ST/TETRIS™ R ST System

510(k) Summary

Indications for Use and Intended Use:
When used as an intervertebral fusion device, the TETRIS™ ST devices are intended for use at one level 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. The lumbar device is to be used in patients who have had six months of non-operative treatment. The devices are intended for use with a supplemental internal fixation system and with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

Description of Modifications:
The TETRIS™ ST and TETRIS™ R ST system is an updated version of a legally marketed previous generation of the device to expand the TETRIS™ product line. The purpose of this submission is for SIGNUS Medizintechnik GmbH to obtain clearance for the manufacturing process change to include additive manufacturing. There are no changes to material or sterilization parameters.

Summary of Technological Characteristics:
The subject TETRIS™ ST and TETRIS™ R ST have 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 that any differences do not impact safety or effectiveness.

Performance Testing – Non-Clinical:
Mechanical testing was conducted to verify that the subject device was substantially equivalent to the predicate device. The test results demonstrated that the subject device complies with ASTM F2077 Standard Test Methods for Intervertebral Body Fusion Devices by performing static and dynamic testing. Static subsidence testing per ASTM F2267-22 and static expulsion testing were performed.

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.