January 25, 2021

SIGNUS Medizintechnik
% J.D. Webb
Official Correspondent
The OrthoMedix Group, Inc.
4313 W. 3800 S.
West Haven, Utah 84401

Re: K203327
Trade/Device Name: VERTACONNECT TLIF cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: October 20, 2020
Received: November 12, 2020

Dear J.D. Webb:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203327

Device Name

VERTACONNECT TLIF cage

Indications for Use *(Describe)*

The VERTACONNECT TLIF cage is indicated for inter-vertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels 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 device is intended for use with supplemental fixation and is intended for use with autograft 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.

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443-6740 EF

510(k) Summary: VERTACONNECT TLIF

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	October 20, 2020
Submitted By	SIGNUS Medizintechnik Industriestrasse 2 D - 63755 Alzenau GERMANY
Primary Contact	J.D. Webb 4313 W. 3800 S West Haven, UT 84401 512-590-5810 Tele e-mail: jdwebb@orthomedix.net
Trade Name	VERTACONNECT TLIF cage
Common Name	Lumbar cage
Classification Name	Intervertebral body fusion device - lumbar
Class	II
Product Code	MAX
CFR Section	21 CFR section 888.3080
Device Panel	Orthopedic
Primary Predicate Device	Varian Cage, Medyssey Co. (K172756)
Additional Predicate Devices	Forza XP, Orthofix (K172696) AMT WAVE Distractable, AMT (K083626)
Device Description	The VERTACONNECT TLIF Spreadable Lumbar Cage is a spacer for implantation in a prepared intervertebral disc space of the lumbar spine. Its design offers stable contact surfaces, toothed implant/bone surfaces and large cage windows. The open implant design supports a bony construction of the intervertebral disc space. The implants consist of a cage and a pre-assembled expansion element.
Materials	Ti-6Al-4V ELI per ASTM F136
Intended Use	The primary function of the interbody implant is to distract the disc space and restore the natural geometry of the disc space as a place holder, supporting the completion of the bony fusion.
Substantial Equivalence Claimed to Predicate Devices	The VERTACONNECT TLIF is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	The VERTACONNECT TLIF cage is indicated for inter-vertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-

	operative treatment. The device is intended for use at either one level or two contiguous levels 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 device is intended for use with supplemental fixation and is intended for use with autograft to facilitate fusion.
Summary of the technological characteristics compared to predicate	Intended Use The VERTACONNECT TLIF and the predicate devices are all intended to be used to maintain adequate disc space until fusion occurs. Indications for Use All of the devices comply with the indications for use specified in 21 CFR section 888.3080 for lumbar interbody fusion devices Material The VERTACONNECT TLIF uses the same material as the predicate device. Design The VERTACONNECT TLIF and the predicate are equivalent in terms of method of expansion, shape, and material. Sizes The VERTACONNECT TLIF and the predicates are equivalent in their dimensions. Strength The VERTACONNECT TLIF has greater or equivalent strength values compared to other devices cleared for use in the lumbar spine.
Non-clinical Test Summary	The following analyses were conducted: • Axial compression, shear-compression, and torsion (ASTM F2077) • Subsidence (ASTM F2267) • Expulsion testing (ASTM F-04.25.0202) • Sterility validation (ISO 11737-2) • Validation requirements for forming, sealing and assembly processes (EN ISO 11607-2) • Seal Strength of Flexible Barrier (ASTM F88/F88M) • Detecting Seal Leaks (ASTM F1929) • Real-time aging (ASTM F1980) • Visual Inspection (ASTM F1886/F1886M-09) • Seal Strength (EN ISO 868-5:2009) • Peelability (EN ISO 868-5:2009) • Atmospheric preconditioning/conditioning – ASTM D4332-14 • Compression test – ASTM D642 • Vibration test frequency – ASTM F999 • Drop test – ASTM D5276 • Vibration test noise – ASTM D4728 • Tests for cytotoxicity (ISO 10993-5) • Endotoxin testing (AAMI ST72) The results of these evaluations indicate that the VERTACONNECT TLIF is as strong or stronger than the predicate devices.
Clinical Test Summary	No clinical studies were performed

Conclusions: Non-clinical and Clinical	SIGNUS Medizintechnik considers the VERTACONNECT TLIF to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use