September 6, 2018

coLigne, AG
% J. D. Webb
Official Correspondent
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, Texas 78681

Re: K173893
Trade/Device Name: Trabis®
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: PLR
Dated: August 3, 2018
Received: August 6, 2018

Dear Mr. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Melissa Hall -S

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K173893

Device Name

Trabis®

Indications for Use *(Describe)*

Trabis® is a vertebral body replacement system indicated for use in the cervical spine (from C2 to T1 vertebral bodies) in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. Trabis® is intended to be used with supplemental fixation cleared by the FDA for use in the cervical spine.

These implants are intended for use with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft, as an adjunct to fusion. Trabis® is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

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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PSC Publishing Se
443-6740 EF

510(k) Summary: Trabis®

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

Date Prepared	September 5, 2018
Submitted By	Robert Lange coLigne, AG Utoquai 43 CH 8008 Zurich Switzerland Telephone: +41 43 343 8000 e-mail: robert.lange@coligne.com
Primary Contact	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199 Tele e-mail: jdwebb@orthomedix.net
Trade Name	Trabis®
Common Name	Vertebral body replacement device
Classification Name	Spinal intervertebral body fixation orthosis
Class	II
Product Code	PLR
CFR Section	21 CFR section 888.3060
Device Panel	Orthopedic
Primary Predicate Device	Cardinal Spine C-VBR (K152568)
Additional Predicate Devices	ostaPek® VBR System (K072326)
Reference Predicate Devices	ACIF (K173148)
Device Description	The devices included in this submission are a subset of the devices that were included in the OstaPek® VBR System, cleared in K072326. The only difference between the Trabis® and the K072326 subset is that the Trabis® VBR are intended for the use in the cervical spine, whereas the devices cleared in K072326 were cleared for use in the thoracolumbar spine. Therefore, the purpose of this 510(k) is to modify the Indications for Use for the subject Trabis®.
Materials	Polyether-ketone-ether-ketone-ketone (ASTM F1876-98) Fiber carbon filaments Gold (ASTM B562-95)
Intended Use	Trabis® provides structural support to the cervical spine by replacing cervical vertebral bodies that have been removed as a result of disease or trauma.

Substantial Equivalence Claimed to Predicate Devices	The Trabis® is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	Trabis® is a vertebral body replacement system indicated for use in the cervical spine (from C2 to T1 vertebral bodies) in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. Trabis® is intended to be used with supplemental fixation cleared by the FDA for use in the cervical spine. These implants are intended for use with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft, as an adjunct to fusion. Trabis® is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.
Summary of the technological characteristics compared to predicate	Intended Use Trabis® and all the predicates have similar intended uses. Materials Trabis® is composed of the same material as the predicate device. Design Features/Functions Trabis® and cited predicate devices share similar basic design features and functions. Dimensions The subject Trabis® system is dimensionally similar to cited predicate devices. Sterilization Trabis® is provided non-sterile and cited predicate devices are sterile and non-sterile for single use only. Performance Specification Mechanical testing confirmed Trabis® demonstrated equivalent performance to the cited predicate device under the same test conditions.
Non-clinical Test Summary	The following analyses were conducted: • Static and dynamic compression per ASTM F2077 • Static and dynamic torsion per ASTM F2077 • Subsidence per ASTM F2267 The results of these evaluations indicate that Trabis® is equivalent to predicate devices.
Clinical Test Summary	A study was presented analyzing the outcome and radiological findings for anterior cervical corpectomy with the use of carbon composite Trabis®, as a support with space for grafts after cervical corpectomy of one or more levels, performed at three centers. All cervical corpectomy cases performed between June 2000 and May 2006 were retrospectively reviewed. Ninety-three patients were treated with the Trabis® after cervical corpectomy of one or more levels for different reasons.
Conclusions: Non-clinical and Clinical	coLigne considers Trabis® to be substantially equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials, performance data, and indications for use.