March 5, 2020

Hyprevention SAS
Cécile Vienney
President/CEO
PTIB - Hopital Xavier Arnozan
Avenue du Haut-Leveque
PESSAC Cedex, 33604 Fr

Re: K191709
Trade/Device Name: V-STRUT© Vertebral Implant
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: NDN, LOD
Dated: June 18, 2019
Received: June 26, 2019

Dear Ms. Vienney:

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

Laura Rose, Ph.D.
Acting Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*
K191709

Device Name
V-STRUT© Vertebral Implant

Indications for Use *(Describe)*
V-STRUT© Vertebral Implant is indicated for use in the treatment of vertebral fractures in the thoracic and lumbar spine from T9 to L5. It is intended to be used in combination with Teknimed F20® bone cement.

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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510(k) Summary

I. SUBMITTER

Hyprevention SAS

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Contact Person : Cécile VIENNEY
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Date Prepared: March 05, 2020

II. DEVICE

Name of Device: V-STRUT© Vertebral Implant
Common / Usual Name: V-STRUT©
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: NDN LOD

III. PREDICATE DEVICE

Primary predicate:

KIVA® VCF Treatment System (K132817)

Reference Device/Clinical comparators:

F20® (K103433),
CORTOSS® Bone Augmentation Material (K080108).

The predicate device has not been subject to any design related recall.

IV. DEVICE DESCRIPTION

V-STRUT© Vertebral Implant is part of V-STRUT© Transpedicular Vertebral System.
V-STRUT© Transpedicular Vertebral System is composed of :

- V-STRUT© Vertebral Implant,
- V-STRUT© Guide Wire,
- V-STRUT© Instrumentation Kit.

V-STRUT© Vertebral Implant is a medical device to be placed in the vertebrae through a minimally invasive procedure. Two devices are implanted in each vertebra to be treated. Each implant is introduced posteriorly through the pedicle up to the anterior vertebral body wall.

The implant is made of radio transparent polymer, PEEK (Polyetheretherketone as per ASTM F2026) and includes two visualizing markers made of tantalum (as per ASTM F560).

V-STRUT© Vertebral Implant exists in 2 different diameters and 5 different lengths to accommodate individual patient's anatomy of thoracic and/or lumbar vertebrae from T9 to L5.

V-STRUT© Vertebral Implant is provided sterile and is not reusable.

V-STRUT© Vertebral Implant is implanted using specific instrumentation provided with the implant and is combined in situ with a Polymethylmethacrylate (PMMA) bone cement, F20® manufactured by Teknimed SA (K103433).

V. INDICATIONS FOR USE

V-STRUT© Vertebral Implant is indicated for use in the treatment of vertebral fractures in the thoracic and lumbar spine from T9 to L5. It is intended to be used in combination with Teknimed F20® bone cement.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following table identifies technological characteristics shared between the primary predicate and the subject device.

Table 1 Comparison between V-STRUT© and its Predicate Device

Element of Comparison	V-STRUT© Transpedicular Vertebral System	KIVA® VCF Treatment System
Classification	Class II (V-STRUT© Vertebral Implant)	Class II
Regulation	21 CFR 888.3027	21 CFR 888.3027
Product Code	NDN, LOD	NDN, LOD
Indications	For use in the treatment of vertebral fractures in the thoracic and lumbar spine from T9 to L5. It is intended to be used in combination with Teknimed F20® bone cement.	For use in the reduction and treatment of spinal fractures in the thoracic and/or lumbar spine from T6-L5. It is intended to be used in combination with Benvenue Vertebral Augmentation Cement Kit.
1. System components	V-STRUT© Transpedicular Vertebral System: - V-STRUT© Vertebral Implant - V-STRUT© Guide Wire - V-STRUT© Instrumentation Kit	KIVA® VCF Treatment System: - KIVA® Implant - KIVA® Deployment System (coil) - Set of Access Instruments

Element of Comparison	V-STRUT© Transpedicular Vertebral System	KIVA® VCF Treatment System
2. Implant materials	PEEK-OPTIMA™ Polymer LT1 (ASTM F2026). Provider INVIBIO. Tantalum markers.	PEEK-OPTIMA™ Polymer LT1 (ASTM F2026) with 15% barium sulphate. Provider INVIBIO. Tantalum markers.
3. Implants sizes	Diameter: 5.5 to 6.5 mm Length: 40 to 60 mm Height: NA	Pedicle access diameter: 5 mm Stacked spiral diameter: 20 mm Height: up to 15 mm
4. Presentation of the device	Sterile, single use device (Implant only)	Sterile, single use device
5. Combination	It is intended to be used in combination with Teknimed F20® PMMA Bone cement (K103433).	It is intended to be used in combination with BENVENUE Medical Vertebral Augmentation Cement Kit.
6. Number of implants	2 permanent devices per vertebrae	1 permanent device per vertebrae
7. Fixation mechanism	In the Vertebral Body. Bone cement injection. Bilateral fracture support. Pedicle anchorage.	In the Vertebral Body. Bone cement injection. Bilateral fracture support.

VII. PERFORMANCE DATA

The following performance testing was conducted to support substantial equivalence determination.

Biomechanical Performance Testing

The safety and performance of V-STRUT© Transpedicular Vertebral System have been substantiated through non-clinical mechanical (static and dynamic) for V-STRUT© Vertebral Implant and functional testing for the whole system. Results of the testing confirm that V-STRUT© Transpedicular Vertebral System can reliably perform as intended.

Biocompatibility

Biocompatibility testing was conducted and documented as recommended by FDA's Guidance for Industry and FDA Staff, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."
V-STRUT© Vertebral Implant was tested to be non-pyrogenic according to USP 42 - NF 37 <151> Pyrogen (Test Rabbit) and BET testing.
V-STRUT© Vertebral Implant was tested to be non-cytotoxic according to ISO 10993-1 "Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity".
V-STRUT© Vertebral Implant is demonstrated to be biocompatible for use in human body and to be as safe as the predicate device.

Sterility

V-STRUT© Vertebral Implant is provided sterile to the end user. This device is for single use only. Each device is sterilized by gamma radiation in accordance with ISO 11137-1 “Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices “ and 11137-2 standards “Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose” to provide a Sterility Assurance Level (SAL) of 10^{-6}.

Shelf-Life

V-STRUT© Vertebral Implant is released with a maximum shelf-life of 5 years from the date of sterilization. The shelf-life was determined in compliance with ASTM F1980 :“Standard Specification for accelerated aging of sterile barrier Systems for medical devices” and by performing a real-time aging study.

Clinical Evaluation

Based on the clinical evaluation V-STRUT© Vertebral Implant has demonstrated to be substantially equivalent to its predicate device KIVA® VCF Treatment System. No additional safety or effectiveness issues as the ones expected and documented in the literature for predicates and references devices have been raised.

VIII. CONCLUSION

V-STRUT© Vertebral Implant compared to the predicate device KIVA® VCF Treatment System has demonstrated is safety, effectiveness and performance as intended. Thus, a conclusion of substantial equivalence to the predicate device is supported.