Hyprevention
Cecile Vienney
CEO
PTIB - Hopital Xavier Arnozan
Avenue du Haut Leveque
Pessac, 33604
France

February 9, 2024

Re: K240084
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: January 3, 2024
Received: January 11, 2024

Dear Cecile 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 (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.

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,

Eileen Cadel -S Digitally signed by Eileen Cadel -S Date: 2024.02.09 09:25:02 -05'00'

for

Colin O'Neill, M.B.E.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240084

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. 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Prepared on: 2024-02-09

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	HYPREVENTION
Applicant Address	PTIB - Hopital Xavier Arnozan Avenue du Haut Leveque PESSAC 33604 France
Applicant Contact Telephone	0017722283218
Applicant Contact	Mrs. Cecile VIENNEY
Applicant Contact Email	c.vienney@hyprevention.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	V-STRUT® Vertebral Implant
Common Name	Polymethylmethacrylate (PMMA) bone cement
Classification Name	Cement, Bone, Vertebroplasty
Regulation Number	888.3027
Product Code(s)	NDN, LOD (CLASS 2) - BONE CEMENT

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K191709	V-STRUT® Vertebral Implant	NDN

Device Description Summary

21 CFR 807.92(a)(4)

V-STRUT© Vertebral Implant 4.5mm diameter is part of V-STRUT© Transpedicular Vertebral System.

V-STRUT© Transpedicular Vertebral System is composed of:
- V-STRUT© Vertebral Implant (K191709, Class II),
- V-STRUT© Guide Wire (Class I),
- V-STRUT© Instrumentation Set (Class I).

V-STRUT© Vertebral Implant 4.5mm diameter 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 4.5mm diameter exists in different lengths to accommodate individual patient's anatomy of thoracic and/or lumbar vertebrae. It is provided sterile. It is implanted using specific instrumentation provided with the implant (V-STRUT© Guide Wire and V-STRUT© Instrumentation Set).

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

V-STRUT© Vertebral Implant is indicated for use in the treatment of vertebral fractures in the thoracic and lumbar spine. It is intended to

be used in combination with Teknimed F20® bone cement.

Indications for Use Comparison 21 CFR 807.92(a)(5)

V-STRUT© Vertebral Implant 4.5mm diameter is intented for use in the treatment of vertebral fractures in the thoracic and lumbar spine, in combination with Teknimed F20® bone cement

The initial intended use in T9 to L5 levels (K191709) is extended to any thoracic or lumbar vertebra.
It was demonstrated through non-clinical mechanical testing and functional testing that V-STRUT© Vertebral Implant 4.5mm diameter is at least equivalent to its predicate device in terms of safety and effectiveness. Thus, a conclusion of substantial equivalence to the predicate device V-STRUT© Vertebral Implant (K191709) is supported.

Technological Comparison 21 CFR 807.92(a)(6)

As its predicate device, V-STRUT© Vertebral Implant 4.5mm diameter is made of PEEK Polymer and implanted with the same instrumentation according to the same surgical steps.

V-STRUT© Vertebral Implant 4.5mm diameter is provided in new sizes. It was demonstrated through non-clinical mechanical testing and functional testing that the V-STRUT© Vertebral Implant 4.5mm diameter is substantially equivalent to the predicate device V-STRUT© Vertebral Implant (K191709).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

V-STRUT© Vertebral Implant 4.5mm diameter substantial equivalence to the predicate device V-STRUT© Vertebral Implant (K191709) is supported by non-clinical mechanical testing (dynamic bending) and functional testing.