May 30, 2025

Amber Implants
Banafsheh Sajadi
Chief Executive Officer
Prinses Beatrixlaan 546
The Hague, 2595 BM
Netherlands

Re: K250637
Trade/Device Name: VCFix Spinal System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: NDN
Dated: February 14, 2025
Received: March 3, 2025

Dear Banafsheh Sajadi:

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,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2025.05.30 14:18:04 -04'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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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.

Submission Number *(if known)*

K250637

Device Name

VCFix Spinal System

Indications for Use *(Describe)*

The VCFix Spinal System is indicated for use in the reduction of vertebral compression fractures that may result from osteoporosis or trauma (fracture types A according to Magerl/AO Spine classification) with or without posterior instrumental fixation, and compression fractures that result from malignant lesions (myeloma or osteolytic metastasis). The VCFix Spinal System is intended to be used in combination with Teknimed F20 bone cement, and to be placed, using a transpedicular approach, in a fractured vertebra from level T9 to L5.

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.

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amber implants

510(k) Summary

Device Trade Name: VCFix Spinal System

Common Name: Implantable Fracture Reduction System

Manufacturer:
Amber Implants
Prinses Beatrixlaan 546,
2595 BM The Hague,
The Netherlands

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Date Prepared: May 30, 2025

Classifications: 21 CFR §888.3027, Polymethylmethacrylate (PMMA) bone cement

Class: II

Product Codes: NDN, Cement, Bone, Vertebroplasty

Indications For Use:
The VCFix Spinal System is indicated for use in the reduction of vertebral compression fractures that may result from osteoporosis or trauma (fracture types A according to Magerl/AO Spine classification) with or without posterior instrumental fixation, and compression fractures that result from malignant lesions (myeloma or osteolytic metastasis). The VCFix Spinal System is intended to be used in combination with Teknimed F20 bone cement, and to be placed, using a transpedicular approach, in a fractured vertebra from level T9 to L5.

Device Description:
The VCFix Spinal System is a cannulated screw-shaped implant with an expandable plate structure and is available in multiple sizes to accommodate varying patient anatomy. A pair of implants are inserted into the pedicles and manipulated with the toolset, resulting in the expansion of the device

to restore the vertebral height. The implant is made of titanium alloy (Ti6Al4V ELI). During the procedure, the surgeon inserts the implants bilaterally through each pedicle of the fractured vertebra and adjusts the height and angle of the device (to correct local kyphosis) based on the unique vertebral fracture of the patient.

The VCFix Spinal System includes sterile, single-use implantation kits and a preparation kit. The kits include a pair of implants and all tools necessary for preparing the implant site and vertebral body expansion. The positioning and expansion of the implant must imperatively be followed by the injection of Teknimed F20 bone cement (K103433) to fixate the restored vertebral body. The bone cement and its delivery system are sold separately.

Predicate Devices:
Amber Implants submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, VCFix Spinal System is substantially equivalent in indications, design principles, and performance to the following legally marketed predicate devices:

Primary Predicate: Stryker SpineJack System (K223294)
Reference Devices: Injection Pin (K221697) by SLK Ortho LLC
Teknimed F20 bone cement (K103433)

Summary of Technological Characteristics:
The subject and predicate devices have the same intended use with similar technological characteristics:

- Intended Use: Intended for the adult population to treat fractures in the thoracolumbar vertebrae caused by osteoporosis, trauma, and tumors, with or without posterior instrumental fixation.
- Principle of Operation: Devices are placed with a minimally invasive, bilateral transpedicular approach, and are inserted through the pedicles into the site in a collapsed form, expanded in the cranio-caudal direction (subject and primary predicate), and then FDA-cleared bone cement is injected through and around the implant to maintain the fracture reduction. Supplemental posterior fixation is placed if necessary.
- Material: Manufactured from titanium alloy.
- Design: Cannulated devices which are offered in a variety of implant sizes to accommodate varying patient anatomy. There are minor differences in the overall geometry of the device, however, the major dimensions fall within the range of previously cleared sizes for the intended use. Compared to the primary predicate, different features of the subject device (e.g., perforated expansion plates, length, diameter) are supported by the reference device and performance testing.
- Sterility: Sterile, for single use only.

Detailed information is provided in the table below.

Characteristics	Subject Device VCFix Spinal System	Primary Predicate Device Stryker SpineJack System (K223294)	Reference Device SLK Ortho LLC, Injection Pin (K221697)	Comparison
Classification	Class II	Class II	Class II	Identical
Regulation	21 CFR 888.3027	21 CFR 888.3027	21 CFR 888.3027	Identical
Product Code	NDN	NDN	NDN, LOD	Identical
Panel	Orthopedic	Orthopedic	Orthopedic	Identical
Intended Use	Intended for the reduction of vertebral compression fractures	Intended for the reduction of vertebral compression fractures	Intended for the reduction of vertebral compression fractures	Identical
Indications for Use	The VCFix Spinal System is indicated for use in the reduction of vertebral compression fractures that may result from osteoporosis or trauma (fracture types A according to Magerl/AO Spine classification) with or without posterior instrumental fixation, and compression fractures that result from malignant lesions (myeloma or osteolytic metastasis). The VCFix Spinal System is intended to be used in combination with Teknimed F20 bone cement, and to be placed, using a transpedicular approach, in a fractured vertebra from level T9 to L5.	The SpineJack Expansion Kit is indicated for use in the reduction of painful osteoporotic vertebral compression fractures, traumatic vertebral compression fractures (Type A fractures according to the AO/Magerl classification) with or without posterior instrumental fixation, and compression fractures that result from malignant lesions (myeloma or osteolytic metastasis). It is intended to be used in combination with Stryker Vertaplex and Vertaplex HV bone cement.	Indicated for use in fractures caused by severe osteoporosis, trauma, and tumors of the thoracic/lumbar spine from T9-L5. Injection Pin is indicated for use in combination with PMMA bone cement (Teknimed F20) for the treatment of fractures caused by trauma, osteoporosis, or tumors in the thoracic/lumbar spine from T9-L5.	Same as primary predicate; specified level T9 to L5. Modified the compatible bone cement trade name which is the same as the reference devices: Teknimed F20 bone cement (K103433).
Target Population	Adult	Adult	Adult	Identical
Anatomical Site	Thoracic and lumbar vertebrae, transpedicular approach	Thoracic and lumbar vertebrae, transpedicular approach	Thoracic and lumbar vertebrae	Identical
Contact	Implant: implant device - permanent contact (> 30 days) with bone/tissue Toolset: external communicating device - limited contact (< 24 hours) with bone/tissue	Implant: implant device - permanent contact (> 30 days) with bone/tissue Toolset: external communicating device - limited contact (< 24 hours) with bone/tissue	Implant: implant device - permanent contact (> 30 days) with bone/tissue	Identical
System Components	VCFix Spinal System consists of: ● VCFix Preparation kit (to prepare the access to the vertebral body) ● VCFix Implantation kit (implant and implant inserter/expander)	SpineJack System consists of: ● SpineJack Preparation kit (to prepare the access to the vertebral body) ● SpineJack Expansion kit (implant and implant inserter/expander)	The Injection Pin system consists of: ● Injection Pin implant ● Injection Pin Screwdriver	Same
Presentation of the Device	Sterile, single use devices	Sterile, single use devices	Sterile, single use devices	Identical

Characteristics	Subject Device VCFix Spinal System	Primary Predicate Device Stryker SpineJack System (K223294)	Reference Device SLK Ortho LLC, Injection Pin (K221697)	Comparison
Materials	● Implant: Ti-6Al-4V (ASTM F3001, ASTM F136) ● Toolset: stainless steel shafts + plastic handles (except for inner dilator made of PPSU)	● Implant: Ti-6Al-4V (ISO 5832-3) ● Toolset: stainless steel shafts + plastic handles	● Implant: Ti-6Al-4V (ISO 5832-3, ASTM F136)	Same-Implant Similar-Instruments
Implant Sizes	7 sizes: Major dimensions: ● Insertion Diameter: o 5mm – 6.5mm ● Total Length in VB: o 41mm – 51.2mm ● Expanding Plate Length: o 14.4mm – 21mm ● Max Expansion Height: o 11.3mm – 16mm	3 sizes: Major dimensions: ● Insertion Diameter (A): o 4.2mm, 5mm, and 5.8mm ● Total Length (B) in VB: o 20mm, 25mm, 28mm ● Expanding Plate Length (B): o 14mm, 19mm, 20mm ● Max Expansion Height (C): o 12.5mm, 17mm, 20mm	Multiple sizes: ● Pin Diameters: o 5 and 6mm ● Total Length: o 31 to 61mm (3mm increments)	Similar and within range of predicates.
Insertion Feature	Spherical head with internal hexagon for mating with inserter	Mates with implant inserter	Spherical head with internal hexagon for insertion screwdriver	Same
Cement Features	Cannulated with perforated structure on the expansion plates	Cannulated with cut-through features	Cannulated and fenestrated screw	Same – all devices are cannulated and allow for cement injection through the length of the device.
Expansion Mechanism	The implant expands in the cranio-caudal direction using a jack mechanism.	The implant expands in the cranio-caudal direction using a jack mechanism.	The implant does not expand.	Similar, both the subject and primary predicate implants gradually extend in the cranio-caudal direction by use of an implant extender instrument to expand.
Anchorage Mechanism	Bone cement and supplemental posterior fixation. Pedicle anchorage to share axial loading between anterior and posterior columns.	Bone cement and supplemental posterior fixation	Bone cement and pedicle anchorage to share axial loading between anterior and posterior columns with bone cement.	Identical

Characteristics	Subject Device VCFix Spinal System	Primary Predicate Device Stryker SpineJack System (K223294)	Reference Device SLK Ortho LLC, Injection Pin (K221697)	Comparison
Principle of Operation	VCFix is implanted into the vertebra after access is established and the site is prepared for implants insertion. Vertebral body access is achieved through bilateral transpedicular positioning of the trocar, followed by guidewire, soft tissue dilation, drill, and template to clean the implant's site. The implant is then inserted into the vertebra *via* the pedicle in a collapsed form, and expanded in situ, to achieve reduction of vertebral compression fractures. Once inserted and expanded, PMMA bone cement is injected into the space within and around VCFix to maintain the fracture reduction. Supplemental posterior fixation is placed if necessary.	The SpineJack is implanted into the vertebra after access is established and the site is prepared for implants insertion. Vertebral body access is achieved through bilateral transpedicular positioning of the trocar, followed by guidewire, drill with working cannula to dilate soft tissue, and template to clean the implant's site. The implant is then inserted into the vertebra *via* the pedicle in a collapsed form, and expanded in situ, to achieve reduction of vertebral compression fractures. Once inserted and expanded, PMMA bone cement is injected into the space within and around the SpineJack to maintain the fracture reduction. Supplemental posterior fixation is placed if necessary.	The Injection Pin is a cannulated fenestrated screw implanted in the spine through a minimally invasive approach. The device allows for injection of PMMA (Teknimed F20) bone cement.	Identical
Surgical Technique Overview	1. VB access and guidewire insertion 2. Dilate soft tissue 3. Drill advanced into VB 4. Template to verify implant length 5. Insert unexpanded VCFix implants into VB 6. VCFix implants expanded 7. Cement injection 8. Supplemental posterior fixation placed (if needed)	1. VB access and guidewire insertion 2. Dilate soft tissue 3. Reamer advanced into VB 4. Template to verify implant length 5. Insert unexpanded SpineJack implants into VB 6. SpineJack implants expanded 7. Cement injection 8. Supplemental posterior fixation placed (if needed)	Implant inserted with injection pin screwdriver followed by cement injection.	Identical to primary predicate
Instruments	Provided in sterile kit: Preparation Kit: ● K-wire ● Two-part dilator ● Drill ● Template Implantation Kit: ● VCFix Implant ● Implant Inserter ● Implant Expander	Provided in sterile kit: Preparation Kit: ● Guidewire ● Access cannula ● Working cannula ● Reamer ● Template Expansion Kit: ● Implant expander tube	Injection pin screwdriver Compatible with previously cleared Teknimed F20 cement injection tools.	Same

Characteristics	Subject Device VCFix Spinal System	Primary Predicate Device Stryker SpineJack System (K223294)	Reference Device SLK Ortho LLC, Injection Pin (K221697)	Comparison
	Compatible with previously cleared Teknimed F20 cement injection tools.	● Handles ● SpineJack Implants ● Quick release pin Cement Injection Tools		
Performance Testing	Mechanical and functional testing was performed to verify the design of the implant, including: ● Lift Force Testing ● ASTM F2077 Static Compression ● ASTM F2077 Dynamic Compression ● ASTM F2077 Static Shear ● ASTM F2077 Dynamic Shear ● ASTM F2193 Static Torsion Test ● ASTM F2193 Screw Driving Torque ● Functionality Tests of VCFix Implant with Cement	Mechanical and functional testing was performed to verify the design of the implant, including: ● Pushing and Recompression Testing (i.e., Lift Force Testing) ● Crimp Force Testing ● Traction Resistance Testing ● Torsion Testing ● Functional Tests of SpineJack Implant with Cement	Unknown	Same – systems demonstrate sufficient strength for the intended use.

The different technological characteristics were found to raise no new questions of safety or effectiveness.

Performance Testing Summary:
All necessary testing has been performed for the worst-case configuration of the VCFix Spinal System to assure substantial equivalence to its predicates and to demonstrate the subject devices perform as intended.

The performance of the VCFix Spinal System in its final, finished configuration are supported by the following:

- Lift Force Testing
- ASTM F2077 Static Compression Testing
- ASTM F2077 Dynamic Compression
- ASTM F2077 Static Shear
- ASTM F2077 Dynamic Shear
- ASTM F2193 Static Torsion and Driving Torque Testing
- Functionality Testing
- Magnetic Resonance Safety Testing to support MR Conditional Labeling
- Biological safety evaluation per ISO 10093-1
- Validation activities to support additive manufacturing processes
- Packaging, sterility, and shelf-life validation activities

Substantial Equivalence Conclusion:
The subject device and the predicate devices have the same intended use/indications for use, sufficiently similar performance, fundamental scientific technology and principles of operation. The data included in this submission demonstrate there are no new risks raised by the subject system and supportive of substantial equivalence. VCFix Spinal System is as safe, as effective, and performs as well as, or better, than the predicate devices.