June 5, 2026

Steps Ortho
% Christine Scifert
Partner
MRC Global, LLC
9085 East Mineral Circle
Suite 110
Centennial, Colorado 80112

Re: K253108
Trade/Device Name: VEOFIX Snap Off Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: September 17, 2025
Received: September 24, 2025

Dear Christine Scifert:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253108

Please provide the device trade name(s).

VEOFIX snap off screw

Please provide your Indications for Use below.

The VEOFIX® snap-off screw is indicated for fixation of bone fractures or for bone reconstruction, including :
- Fixation of small bone fragments
- Weil osteotomy
- Mono-cortical fixation
- Osteotomies and fractures fixation in the foot

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Prepared: June 5, 2026

I. SUBMITTER

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II. DEVICE

Name of Device:	VEOFIX® snap-off screw
Common/Usual Name:	Screw, Fixation, Bone
Regulation Numbers:	21 CFR 888.3040
Regulation Name:	Smooth or threated metallic bone fixation fastener
Regulatory Class:	II
Product Codes:	HWC, Screw, fixation, bone

III. PREDICATE DEVICE

Primary Predicate	SPIN® snap-off screw K011946

IV. DEVICE DESCRIPTION

The VEOFIX® snap-off screw is manufactured in TA6V (the composition is compliant with ISO 5832-3 standard).

The VEOFIX® snap-off screw has two distinct parts, the cartridge and the implantable screw. The cartridge can be combined with the adapter using a handle.
The parts will separate when the head of the screw is in contact with the bone
The VEOFIX® Snap-off screw is available in 4 sizes of the same diameter Ø 2mm (11 mm, 12 mm, 13 mm and 14 mm).

V. INDICATIONS FOR USE

The VEOFIX® snap-off screw is indicated for fixation of bone fractures or for bone reconstruction, including :

- Fixation of small bone fragments
- Weil osteotomy
- Mono-cortical fixation
- Osteotomies and fractures fixation in the foot

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

VEOFIX® snap-off screw and SPIN® snap-off screw are both intended to be implanted for fixation of bone fractures or for bone reconstruction. VEOFIX® snap-off screw has the same technological characteristics to the predicate SPIN® snap-off screw. Specifically, both devices have the same design (self-drilling and self-tapping snap-off screw) and are placed permanently in the foot. Both subject device and predicate device are comprised of Titanium Alloy which further support the substantial equivalence. The additional diameter available for the SPIN® snap-off screw do not raise new types of questions of safety or effectiveness either, as both devices are designed to offer the surgeon to accommodate individual patient anatomy. The key questions of safety and effectiveness for both devices are the same, i.e., whether the implant can be correctly implanted, whether the implant can perform the stabilization and attachment of the bones to each other to achieve bone fusion.

In addition, bench testing confirms that the technological characteristics of VEOFIX® snap-off screw is appropriate for its intended use and functions as intended. Thus, a conclusion of substantial equivalence is supported.

VII. PERFORMANCE TESTING

The following performance testing was conducted to support substantial equivalence. Torsional yield strength testing was compared against the predicate device. Pullout strength, driving and removal torque testing was compared against the FDA guidance document, “Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway”.

Performance Testing

Mechanical and functional testing was performed to verify the design of the implant, including:

- Pullout strength
- Driving and removal torques
- Torsional resistance

Biocompatibility

Biocompatibility testing was conducted in accordance with NF EN ISO 10993-1 :2020 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process and NF EN ISO 14971 :2019 Medical devices - Application of risk management to medical devices.

Sterility

Sterilization validation testing was performed in accordance with NF EN ISO 11137-1:2016 "Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices."

MR Compatibility

VEOFIX® snap-off screw has been evaluated for safety in the magnetic resonance environment and has been determined to be MR Conditional.

STEPS ORTHO implant can be scanned safely after implantation under specific conditions mentioned in the Instructions for Use.

Pyrogenicity

Endotoxin testing was completed per USP Chapter <85>.

VIII. CONCLUSIONS

The differences that exist between VEOFIX® snap-off screw and its predicate do not raise different questions of safety or effectiveness. The results of performance testing demonstrate that VEOFIX® snap-off screw will perform safely as intended and support a determination of substantial equivalence to the predicate device which is marketed for the same intended use.