



December 5, 2025

3D Systems, Inc.
Ashley Dawson
Director, Regulatory Affairs
5381 South Alkire Circle
Littleton, Colorado 80127

Re: K250711

Trade/Device Name: VSP Orthopedics System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories

Regulatory Class: Class II

Product Code: PBF

Dated: November 4, 2025

Received: November 4, 2025

Dear Ashley Dawson:

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,

 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

Submission Number (if known)

K250711

Device Name

VSP Orthopedics System

Indications for Use (Describe)

The VSP Orthopedics System is intended to be used as a surgical instrument to assist in preoperative planning and/or in guiding the marking of bone and/or in guiding surgical instruments in non-acute, non-joint replacing osteotomies in the distal femur, tibia, and non-sacrum pelvis of adults and skeletally mature adolescents of normal stature.

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

1. INTRODUCTION

This document contains the 510(k) summary for the VSP Orthopedics System. The content of this summary is based on the requirements of 21 CFR 807.92.

2. SUBMITTER

Name: 3D Systems, Inc.

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Phone: (720) 643-1001
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Official Contact: Dr. Ashley Dawson
Director of Regulatory Affairs

Date Prepared: December 1, 2025

3. DEVICE

Trade Name: VSP Orthopedics System

Common Name: Orthopaedic Surgical Planning and Instrument Guides

Classification Name: Single/multiple component metallic bone fixation appliances and accessories

Classification: Class II, 21 CFR 888.3030

Product Code: PBF

4. PREDICATE DEVICE

Predicate Device: K211244 VSP Orthopedics System, Product Code PBF

5. DESCRIPTION OF THE DEVICE

The VSP Orthopedics System is intended to assist a surgeon with pre-operative planning and transfer of the pre-operative plan to the surgery in orthopedic procedures. The system contains several physical and digital outputs including patient-specific anatomical models, templates, and guides (physical outputs); and patient-specific surgical plans and digital files (digital or documentation outputs).

Outputs of the VSP Orthopedics System are designed with physician input and reviewed by the physician prior to finalization and distribution.

The VSP Orthopedics System also contains Stainless Steel Drill Inserts (VSP Orthopedics System Accessories) which are intended to be used by the physician to guide drilling activities during the surgical procedure. The inserts fit into a standard hole in the cutting / drill guides and can be used across all VSP Orthopedics System guides and templates.

6. INTENDED USE/INDICATIONS FOR USE

The VSP Orthopedics System is intended to be used as a surgical instrument to assist in preoperative planning and/or in guiding the marking of bone and/or in guiding surgical instruments in non-acute, non-joint replacing osteotomies in the distal femur, tibia, and non-sacrum pelvis of adults and skeletally mature adolescents of normal stature.

7. INDICATIONS FOR USE COMPARISON

The proposed changes to the indications for use to include pediatric use is substantially equivalent to the predicate device. The clinical data supporting safety and effectiveness in the pediatric population includes literature and Compassionate Use data.

8. TECHNOLOGICAL COMPARISON

The Subject Device has the same technological characteristics (i.e., design, material, chemical composition, principle of operation, etc.) as the Predicate Device.

9. NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY

Nonclinical testing was not performed as the technical characteristics of the Subject Device are unchanged.

Clinical testing included a systematic literature review and analysis and review of Compassionate Use cases in the intended patient population.

10. CONCLUSION

Based on a comparison of the intended use, indications for use, technological characteristics, and Clinical testing, the VSP Orthopedics System is substantially equivalent to the Predicate Device in the intended patient population.