



April 16, 2026

Spinal Simplicity
Adam Rogers
Vice President of Regulatory and Engineering
6363 College Blvd.
Suite 320
Overland Park, Kansas 66211

Re: K253523

Trade/Device Name: Freedom DS™ Decompression System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: November 12, 2025
Received: November 13, 2025

Dear Adam Rogers:

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,

JESSE MUIR - Digitally signed by JESSE
MUIR -S
S Date: 2026.04.16
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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
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.

K253523

?

Please provide the device trade name(s).

?

Freedom DS™ Decompression System

Please provide your Indications for Use below.

?

The Freedom DS™ Decompression System is used to perform decompressive procedures for the treatment of various lumbar spinal conditions.

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

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Spinal Simplicity
Applicant Address	6363 College Blvd Ste 320 Overland Park KS 66211 United States
Applicant Contact Telephone	913-451-4414
Applicant Contact	Mr. Adam Rogers
Applicant Contact Email	arogers@spinalsimplicity.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Freedom DS™ Decompression System
Common Name	Arthroscope
Classification Name	Arthroscope
Regulation Number	888.1100
Product Code(s)	HRX, HAE

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K233800	Vertos mild Device Kit (MDK-002)	HRX

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The Freedom DS™ Decompression System is a set of surgical instruments used to accomplish a lumbar decompressive procedure in a skeletally mature patient by accessing the treatment zone, retracting surrounding tissue, removing portions of the lamina/bony anatomy and resecting soft tissue (e.g., fat, ligamentum flavum, etc.). The Freedom DS Decompression System consists of one each of the following instruments: Access Instrument, Reamer, Bone Removal Instrument and Tissue Removal Instrument. The Freedom DS Decompression System is supplied sterile and is single use. The decompressive procedure is completed using a minimally invasive, posterior surgical approach supplemented by fluoroscopic imaging for landmark identification and control of instrument positioning.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The Freedom DS™ Decompression System is used to perform decompressive procedures for the treatment of various lumbar spinal conditions.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The Freedom DS Decompression System has the same indications for use as the predicate device.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The Freedom DS Decompression System has the same indications for use with similar technological characteristics (e.g., instruments used for targeting, access, tissue cutting/removal), materials, surgical approach and principles of operation as the cleared predicate device.

The following technological differences exist between the subject and predicate devices:

- Use of instrument-based depth control mechanisms
- Inclusion of a cutting angle orientation control feature for ergonomic handling
- Incorporation of a quick release locking mechanism in the working channel grip component
- Geometric differences in the cutting instrument interfaces

Differences between the subject and predicate devices are minor and do not raise new questions of safety or effectiveness. Performance testing demonstrates that the device has mechanical performance substantially equivalent to that of the predicate.

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

The following reports were provided to support the safety and efficacy of the Freedom DS Decompression System:

Biocompatibility Report
Sterility Report
Stability and Shelf Life Report
Mechanical Performance Testing of Freedom DS Instruments
Cadaver Validation Report

Clinical data was not necessary for this submission.

Spinal Simplicity concludes that the performance data provided in this 510(k) application demonstrates that the Freedom DS Decompression System is capable of performing as intended and is as safe and effective as the legally marketed predicate device.