



March 27, 2026

Synergy Spine Solutions, Inc.
% Veronica Downen
MCRA, LLC
803 7th St. NW
Washington, District of Columbia 20001

Re: K253392

Trade/Device Name: Synergy Disc Instruments

Regulation Number: 21 CFR 888.4515

Regulation Name: Orthopedic Manual Surgical Instrumentation For Use With Total Disc Replacement
Devices

Regulatory Class: Class II

Product Code: QLQ

Dated: February 27, 2026

Received: February 27, 2026

Dear Veronica Downen:

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,

MAZIAR SHAH-
MOHAMMADI -S

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

Indications for Use

510(k) Number (if known)
K253392

Device Name
Synergy Disc Instruments

Indications for Use (Describe)

The Synergy Disc Instruments are intended for the placement, positioning, and removal of the Synergy Disc.

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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510(k) Summary

Device Trade Name: Synergy Disc Instruments

Device Common Name: Manual instruments designed for use with total disc replacement devices

Manufacturer: Synergy Spine Solutions Inc.
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Louisville, CO 80027

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Date Prepared: March 21, 2026

Classifications: 21 CFR 888.4515; Orthopedic manual surgical instrumentation for use with total disc replacement devices

Class: II

Product Codes: QLQ

Primary Predicate: Centinel Spine prodisc C SK, prodisc C Nova, and prodisc C Vivo Instruments (K221848)

Indications For Use:

The Synergy Disc Instruments are intended for the placement, positioning, and removal of the Synergy Disc.

Device Description:

The Synergy Disc Instruments are a collection of reusable instruments designed for use with the Synergy Disc during the implantation procedure and, if necessary, device removal. Synergy Spine Solutions instruments and implants are not compatible with implants or instruments from other manufacturers unless otherwise specified. The Synergy Disc Instruments are made from

various Stainless Steels (Grades 17-4, 18-8, 301, 302, 316, 465) and polymers, including High Density Polyethylene (HDPE) and medical grade Polyphenylsulfone (PPSU), as described in such standards as ASTM A564, ASTM A276, ASTM A666, ASTM F899, and ASTM D6712.

Predicate Device:

The purpose of this Traditional 510(k) is to demonstrate that the Synergy Disc Instruments are substantially equivalent to predicate devices for the purpose of introducing the system to interstate commerce. It has been determined that the Synergy Disc Instruments are substantially equivalent to the following predicate:

- **Primary Predicate:** Centinel Spine prodisc C SK, prodisc C Nova, and prodisc C Vivo Instruments (K221848)

Overall, the Synergy Disc Instruments share the following similarities to the predicate product:

- shares the same intended use
- shares the same indications for use
- incorporates similar materials
- has identical sterilization process
- has identical conditions of use

Performance Testing Summary:

The following bench testing has been conducted on the Synergy Disc Instruments:

- Performance Testing
 - Retainer and Pin Verification Test
 - Pin and Driver Verification Test
 - Pilot Cutter Test
 - Modular Depth Stop Test
 - Life and Durability Test
- Usability/ Cadaver Testing

Substantial Equivalence:

The subject devices were demonstrated to be substantially equivalent to the predicates cited with respect to indications, design materials, function, manufacturing, and performance. The non-clinical tests performed by the company demonstrated that the Synergy Disc Instruments are able to perform as intended and are substantially equivalent to the predicate devices.

Conclusion:

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods. The data included in this submission demonstrates substantial equivalence to the predicate devices listed above.