



March 25, 2026

SpinePoint, LLC
Lali Sekhon, MD, PhD, MBA
Founder and CMO
12975 Silver Wolf Rd.
Reno, Nevada 89511

Re: K252432
Trade/Device Name: Flex-Z™ Cervical Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: February 26, 2026
Received: February 27, 2026

Dear Dr. Sekhon:

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,

Brent Showalter -S

Brent Showalter, Ph.D.

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

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

K252432

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Please provide the device trade name(s).

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Flex-Z™ Cervical Cage

Please provide your Indications for Use below.

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The SpinePoint Flex-Z™ Cervical Cage is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies) at multiple contiguous levels from C2-T1 spine using an anterior approach. The SpinePoint Flex-Z™ Cervical Cage is intended to be used with supplemental fixation systems and with allograft/allogenic bone graft, comprised of cancellous, cortical, and corticocancellous bone to facilitate fusion. Patients should receive 6 weeks of non-operative treatment prior to treatment with the SpinePoint Flex-Z™ Cervical Cage.

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)

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510(k) Summary

Contact Details

Applicant Name	SpinePoint, LLC
Applicant Address	12975 Silver Wolf Rd. Reno NV 89511 United States
Applicant Contact Telephone	775-815-8097
Applicant Contact	Dr. Lali Sekhon
Applicant Contact Email	sekhon@spinepointusa.com

Device Name

Device Trade Name	Flex-Z™ Cervical Cage
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral Fusion Device With Bone Graft, Cervical
Regulation Number	888.3080
Product Code(s)	ODP

Legally Marketed Predicate Devices

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K223731	NuVasive Modulus-C Interbody System	ODP
K183705	IdentiTi Porous Ti Interbody System	ODP
K191812	ADI Cervical Interbody Fusion Device	ODP

Device Description Summary

The SpinePoint Flex-Z™ Cervical Cage is an intervertebral body fusion device additively manufactured Grade 23 titanium alloy (Ti-6Al-4V ELI) per ASTM F3001. The device consists of lattice and a z-shaped frame to improve the stability of the spine while supporting fusion. Additional features include a graft window for packing bone graft and porous endplates to ensure placement is maintained after insertion and aid in osseointegration.

The Flex-Z™ Cervical Cage is available in multiple footprints, heights, and degrees of lordosis to accommodate patient anatomies and surgical approach. Implants are provided sterile in sterile packaging, are single-use only, and are intended to be used with FDA-cleared fixation devices such as an anterior cervical plate system.

Intended Use/Indications for Use

The SpinePoint Flex-Z™ Cervical Cage is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies) at multiple contiguous levels from C2-T1 spine using an anterior approach. The SpinePoint Flex-Z™ Cervical Cage is intended to be used with supplemental fixation systems and with allograft/allogenic bone graft, comprised of cancellous, cortical, and corticocancellous bone to facilitate fusion. Patients should receive 6 weeks of non-operative treatment prior to treatment with the SpinePoint Flex-Z™ Cervical Cage.

Indications for Use Comparison

The SpinePoint Flex-Z™ Cervical Cage has identical or similar indications for use as the predicate devices.

Technological Comparison

The SpinePoint Flex-Z™ Cervical Cage has similar technological characteristics, surgical approach, materials, range of sizes, design, and principles of operation as the predicate devices. Any differences in technological characteristics do not raise different questions of safety or effectiveness. Performance testing demonstrates the device has mechanical performance substantially equivalent to that of the predicate devices.

Non-Clinical Summary & Conclusions

Mechanical testing was performed to demonstrate substantial equivalence using ASTM F2077-22 Static Axial Compression, Static Compression Shear, Static Torsion, Dynamic Axial Compression, Dynamic Compression Shear, and Dynamic Torsion, ASTM F2267-24 Subsidence, Expulsion, and ASTM F1798 Taber Abrasion.

The results of the mechanical testing showed that the worst-case devices were substantially equivalent to legally marketed devices.