



September 29, 2026

DJO, LLC
% Kristin Duggan
Partner
Hogan Lovells Cadwalader US LLP
555 Thirteenth Street North West
Washington, District of Columbia 20004

Re: K262721

Trade/Device Name: Spinalogic Bone Growth Stimulator
Regulation Number: 21 CFR 890.5870
Regulation Name: Non-Invasive Bone Growth Stimulator
Regulatory Class: Class II
Product Code: LOF
Dated: July 31, 2026
Received: July 31, 2026

Dear Kristin Duggan:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81.

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.

K262721

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Please provide the device trade name(s).

?

Spinalogic Bone Growth Stimulator

Please provide your Indications for Use below.

?

The Spinalogic is a portable, battery powered, micro-controlled, noninvasive bone growth stimulator indicated for skeletally mature patients as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels and adjunct use following primary anterior cervical discectomy and fusion (ACDF) surgery of 2 motion segments (3 vertebrae) from C4 - C7.

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](#))

?

Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☐ Children (2 years old to < 12 years old)

☐ Adolescents (12 years old to < 22 years old)

☒ Adults (22 years old and greater)

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Spinalogic® Bone Growth Stimulator

510(k) Summary

Prepared in accordance with 21 CFR 807.92

510(k) Owner / Submitter	DJO, LLC
Address	3151 Scott St. Vista, CA 92081
Telephone	1-945-334-7958
Contact Person	Mitchell A. Dhority
Email	Mitchell.Dhority@enovis.com
Date Summary Prepared	September 29, 2026

1. Device Name and Classification [21 CFR 807.92(a)(2)]

Trade / Proprietary Name	Spinalogic Bone Growth Stimulator
Common Name	Non-invasive bone growth stimulator
Classification Name	Stimulator, bone growth, non-invasive
510(k) Number	K262721
Regulation Number	21 CFR 890.5870
Product Code / Device Class	LOF / Class II (Special Controls)

2. Legally Marketed Predicate Device [21 CFR 807.92(a)(3)]

The subject device is compared to the following legally marketed predicate device:

Predicate Device	Spinalogic Bone Growth Stimulator
Predicate Manufacturer	DJO, LLC
Predicate Submission / Authorization	P910066/S011 (reclassified into Class II via Final Order 91 FR 20352, effective May 18, 2026)
Classification Name	Stimulator, bone growth, non-invasive
Regulation / Product Code	21 CFR 890.5870 / LOF

3. Device Description [21 CFR 807.92(a)(4)]

Spinalogic is a portable, battery-powered, micro-controlled, non-invasive bone growth stimulator intended to provide adjunctive electromagnetic stimulation to support bone healing following spinal fusion surgery. The device uses Combined Magnetic Field (CMF) technology to generate a low-energy electromagnetic field at the treatment site. The stimulation is delivered externally, without implanted components, and is intended for home use under prescription and physician direction.

The system consists of a control unit/waveform generator, treatment coil or applicator assembly, patient-contacting support/positioning components, user interface indicators/prompts, power source, and labeling/instructions for use. During treatment, the applicator is positioned externally over the spinal fusion site. The device delivers a programmed CMF signal for the prescribed daily treatment duration of 30 minutes, consistent with the operating specifications and labeling.

The scientific concept supporting the device is the use of externally applied electromagnetic fields to promote osteogenesis as an adjunct to the primary surgical treatment.

Spinalogic was FDA approved on December 17, 1999 (P910066/S011) as a portable, battery-powered, micro-controlled, noninvasive bone growth stimulator indicated as an adjunct electromagnetic treatment to primary lumbar spinal fusion surgery for one or two levels. Spinalogic is part of a larger family of CMF Bone Growth Stimulator devices covered under PMA P910066, approved March 4, 1994. No modifications to the physical components of the device, its software, or manufacturing controls that affect consistent treatment delivery are made as part of this submission. The only changes are to the labeling and indications for use.

4. Intended Use / Indications for Use [21 CFR 807.92(a)(5)]

The Spinalogic Bone Growth Stimulator is intended to provide non-invasive electromagnetic stimulation to promote osteogenesis as an adjunct treatment for spinal fusion. The indications for use of the predicate approved Spinalogic device are as follows:

- The Spinalogic is a portable, battery powered, micro-controlled, noninvasive bone growth stimulator indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels.

This 510(k) notice updates the indications for use to the following:

- The Spinalogic is a portable, battery powered, micro-controlled, noninvasive bone growth stimulator indicated for skeletally mature patients as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels and adjunct use following primary anterior cervical discectomy and fusion (ACDF) surgery of 2 motion segments (3 vertebrae) from C4 - C7.

5. Technological Characteristics Compared with Predicate [21 CFR 807.92(a)(6)]

Both Spinalogic and the predicate device use non-invasive stimulation technology to promote bone growth as an adjunct to spinal fusion. The subject device remains the same portable, battery powered, micro-controlled, non-invasive bone growth stimulator as the predicate. The device components, materials, patient-contacting elements, energy source, output characteristics, accessories, software, manufacturing processes, and fundamental technological characteristics are unchanged.

Because there are no technological modifications, the subject device does not include new components or accessories that are absent from the predicate device. The expanded indication is supported by clinical and labeling information described below. The device continues to perform in accordance with its established specifications and does not raise different types of safety and effectiveness questions from the predicate device.

	SPINALOGIC (Predicate: P910066/S011)	SPINALOGIC (Subject Device: K262721)
Intended Use	Non-invasive stimulation to promote osteogenesis as an adjunct to spinal fusion/clinical management	No change

	SPINALOGIC (Predicate: P910066/S011)	SPINALOGIC (Subject Device: K262721)
Indications for Use	The Spinalogic is a portable, battery powered, micro-controlled, noninvasive bone growth stimulator indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels.	The Spinalogic is a portable, battery powered, micro-controlled, noninvasive bone growth stimulator indicated for skeletally mature patients as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels and adjunct use following primary anterior cervical discectomy and fusion (ACDF) surgery of 2 motion segments (3 vertebrae) from C4 - C7.
User Population	Physicians (Prescription Use Only)	No change
Technological Characteristics	The Bone Growth Stimulator emits a sinusoidal magnetic field with a peak to peak amplitude of 400mG and a 200mG D.C. offset at a frequency of 76.6 Hz. Magnetic energy is considered to be non- ionizing radiation.	No change
Accessories	Not applicable	No change
Dimensions (l x w x h)	11 in x 12 in x 1.5 in (28 cm x 31 cm x 4 cm)	No change
Weight	2.0 lbs (0.9 kg)	No change
Power Source	Battery operated, replaceable, 9 volts direct current. Battery operated device (9V standard battery), not to use lithium batteries.	No change
Safety Features	Unit is fully enclosed and not serviceable by user (aside from 9V battery installation); IP22 compliant	No change
Software	Yes, device uses firmware to generate magnetic field treatment, maintain treatment record, daily treatment time countdown	No change
Sterilization	Non-sterile; no sterilization is required	No change

6. Nonclinical Performance Data [21 CFR 807.92(b)(1)]

The Spinalogic Bone Growth Stimulator incorporates the same technological features as the predicate and the treatment signal is identical, so no additional non-clinical data was required to support substantial equivalence. A series of toxicological studies on isolated cells, as well as animals, were performed to evaluate the safety of combined static and dynamic magnetic fields. Further, in vitro and in vivo studies were conducted to determine whether the application of these magnetic fields in animal models would stimulate bone healing and other related biological responses. Many of these previous laboratory experiments included whole body exposure to the test animals (and thus included vertebrae and nerve tissue). The device has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices to EN 60601-1:2006+A1:2013+AC:2014+A12:2014 +A2:2020, IEC 60601-1-2:2015+A1:2020, IEC 60601-1-6:2010 + A1:2013, IEC 60601-1-11:2015, and IEC 62304:2006 + A1:2015. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

7. Clinical Performance Data [21 CFR 807.92(b)(2)]

Lumbar Indications (P910066). The supporting clinical data was derived from a single prospective, randomized, double-masked, placebo-controlled trial where the placebo was a non-functional (sham) Spinalogic device. Spinalogic was studied as an adjunct to surgery in 243 patients undergoing lumbar spine fusion (one or two levels between L3 and S1). Of the 201 subjects evaluable at the 9 months study endpoint, fusion success was determined for 64% of Spinalogic device users and 43% of the placebo controls. This positive treatment effect was statistically significant for the overall population and for women but not for males. Spinalogic was approved as an adjunct treatment to primary lumbar spinal fusion surgery for one or two levels.

Cervical Indications (K262721). The supporting clinical data was derived from a single retrospective, controlled, real-world evidence (off-label clinical practice) study enrolling 240 patients at 2 US sites. Spinalogic was evaluated as an adjunctive post-operative treatment for patients undergoing 2-levels (consecutive or adjacent) or 1-level (with presence of at least one risk factor for fusion) anterior cervical discectomy and fusion (ACDF). Study success was determined at 12 months based on the proportion of subjects that achieved radiographic fusion. Of the 110 12-months completers (subjects who had interpretable radiographic studies at the 12-months visit), 87.5% (56/64) of the Spinalogic treated and 73.9% (34/46) of the untreated controls achieved radiographic fusion. Treatment-related improvement in radiographic fusion was not statistically significant in the unadjusted analysis performed for the 12-months completers (13.6% $p = 0.077$), diabetic subjects (20/24 versus 15/19 $p = 0.716$) and active smokers (23/29 versus 19/29 $p = 0.234$). Female subjects (91.3% versus 73.1% $p = 0.009$) benefited more from treatment than males (74.2% versus 72.5% $p = 0.844$).

When variables such as age, sex, BMI, risk factors and 2-level fusions were controlled for in a post-hoc linear regression model, there was a statistically significant improvement in fusion rates for the Spinalogic treatment group versus those in the full control group ($p < 0.05$); individuals who received the Spinalogic treatment were 2.35 times more likely to achieve fusion. The study did not observe treatment-related improvement in secondary non-fusion outcomes (Visual Analogue Scale - pain, Odom Criteria). Study safety was consistent with that reported for Spinalogic's lumbar spine study with no identified serious adverse events related to device use.

In conclusion, statistical significance for the pre-specified primary analysis was not obtained within this real-world evidence study; however, the secondary effectiveness analyses provide evidence for device-related improvement in radiographic fusion at 12 months of follow-up.

8. Conclusions [21 CFR 807.92(b)(3)]

The clinical data collected on the cervical indication demonstrate that the subject device is substantially equivalent to the predicate device identified.