August 27, 2025

LESspine Innovations
℅ Hannah Taggart
Regulatory Associate
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K243774
Trade/Device Name: ELID (Endoscopic Less Invasive Decompression) System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: August 1, 2025
Received: August 1, 2025

Dear Hannah Taggart:

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,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2025.08.27 14:42:07 -04'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair, and Trauma Devices
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Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243774

Device Name

ELID (Endoscopic Less Invasive Decompression) System

Indications for Use *(Describe)*

The ELID (Endoscopic Less Invasive Decompression) system intended to provide lumbar decompression of the spine to treat various spinal condition(s) using minimally invasive techniques and instrumentation.

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.

K243774 510(K) SUMMARY

Submitter's Name:	LESspine Innovations
Submitter's Address:	200 Summit Drive, Suite 505 Burlington MA 01803
Submitter's Telephone:	617-820-2900
Contact Person:	Hannah Taggart, MS Empirical Technologies 719- 457-1152 htaggart@empiricaltech.com
Date Summary was Prepared:	August 1, 2025
Trade or Proprietary Name:	ELID (Endoscopic Less Invasive Decompression) System
Device Classification Name:	Arthroscopic Accessories
Classification & Regulation #:	Class II per 21 CFR §888.1100
Product Code:	HRX
Classification Panel:	Orthopedic

DEVICE DESCRIPTION AND TECHNOLOGY

The ELID (Endoscopic Less Invasive Decompression) System consists of instrumentation intended to aid the user in completing steps necessary to perform lumbar decompression. Instruments include a bone needle, flat blade dilator, dilator tubes, and rongeurs. Instruments in the ELID (Endoscopic Less Invasive Decompression) System are supplied non-sterile, reusable, and manufactured from aluminum per ASTM B211, Nitinol per ASTM 2063, or stainless steel per ASTM A564.

INDICATIONS FOR USE

The ELID (Endoscopic Less Invasive Decompression) System is intended to provide lumbar decompression of the spine to treat various spinal condition(s) using minimally invasive techniques and instrumentation.

TECHNOLOGICAL CHARACTERISTICS

The predicates included in this submission were selected based on the best practices described in the FDA Draft Guidance document *Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission*. The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Device Components

Predicate Devices

510k Number	Trade or Proprietary	Manufacturer	Product Code	Predicate Type
K233800	Vertos mild Device Kit	Vertos Medical	HRX, HAE	Primary
K993012/K002931	METRx™ System	Medtronic Sofamor Danek, Inc.	HRX	Additional
K210741	KLS Martin Neuro Rongeurs	KLS-Martin L.P.	HAE	Reference
K152734	Vitalitec Kerrison Rongeurs	Vitalitec Medizintechnik GmbH	HAE	Reference

		ELID System (Subject Device)	Vertos Medical *mild* Device Kit (K233800)	Medtronic Sofamor Danek, Inc., METRx™ System (K993021/K002931)	KLS Martin Neuro Rongeurs (K210741)	Vitalitec Kerrison Rongeurs (K152734)
Indications for Use		The ELID (Endoscopic Less Invasive Decompression) System intended to provide lumbar decompression of the spine to treat various spinal condition(s) using minimally invasive techniques and instrumentation.	The Vertos Medical *mild* Device Kit is a set of specialized surgical instruments intended to be used to perform lumbar decompressive procedures for the treatment of various spinal conditions.	The METRx™ Microscope is indicated for visualization of the surgical field in any area of the body cut open during a surgical procedure. When used in the cervical, thoracic, or lumbar spine either from an anterior or posterior direction, for example, the METRx™ Microscope and accessories are intended to aid the surgeon's visualization of the surgical area and allow him/her to perform any type of surgical spinal procedure such as herniated disc repair, visualization of the circumferential decompression of the nerve roots, aiding in the search and removal of nucleus material, spinal fusion, or insertion of spinal implants.	The KLS Martin Neuro Rongeurs are manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column in patients two years of age or older.	Vitalitec Kerrison Rongeurs are manually operated reusable surgical instruments used for cutting or biting bone during surgery involving the skull or spinal column.
Classification		888.1100	888.1100	888.1100	882.4840	882.4840
Product Code		HRX, HAE	HRX, HAE	HRX	HAE	HAE
Sterility		Non-sterile, reusable	Sterile, single-use	Non-sterile	Non-sterile, reusable	Non-sterile, reusable
Device Components	**Navigation to Site**	**Bone Needle** Material: Stainless Steel **Guidewire** Material: Nitinol per ASTM F2063 Size: Ø1.5mm x 500 mm	***mild* Initiator** Material: Acrylonitrile butadiene styrene, stainless steel, polycarbonate, thermoplastic elastomer	**Guidewire** Material: Unknown Sizes: Ø1.57 mm x 300 mm	**Not Applicable**	**Not Applicable**
	Dilation of Site	**Flat Blade Dilator** Material: 17-4 PH SS per ASTM A564 **Dilator Tubes** Material: 7075-T6 Al per ASTM B211 Sizes: Ø6.0mm, Ø8.0mm, Ø 12.9mm, Ø 16.3mm	***mild* Access Auger** Material: Stainless Steel	**Dilators** Material: Unknown Sizes: Ø5.3 mm – Ø24.8 mm	**Not Applicable**	**Not Applicable**
	Tissue/Bone Removal	**Kerrison Rongeur** Material: Stainless Steel Sizes: 3mm, 5mm, 4mm, 6mm	***mild* Bone Rongeur** Material: Stainless Steel ***mild* Tissue Sculptor** Material: Acrylonitrile butadiene styrene, stainless steel, nylon, zinc-plated wire	**Kerrison Rongeur** Material: Unknown Sizes: 1mm, 2mm, 3mm, 4mm, 5mm	**Kerrison Rongeur** Material: Stainless Steel, TiAlN coating, gold plating Sizes: 1mm to 6mm	**Kerrison Rongeur** Material: Stainless Steel, TiAlN coating Sizes: 1mm to 6mm

The subject device is different from the predicate device in that the subject system includes a flat blade dilator and guidewire which the predicate devices do not use during the decompression procedure. Both the subject flat blade dilator and guidewire have been cleared and remain unchanged since their previous submission.

PERFORMANCE DATA

The ELID (Endoscopic Less Invasive Decompression) System has been tested in the following test modes:

- Cleaning Validation
- Sterilization Validation
- Biocompatibility
- Usability Testing
- Particulate Analysis per ASTM F1877

The results of this non-clinical testing show that the strength of the ELID (Endoscopic Less Invasive Decompression) System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the ELID (Endoscopic Less Invasive Decompression) System is substantially equivalent to the predicate device.