June 16, 2026

Empirical Spine
Louie Fielding
COO
18655 Madrone Pkwy, Suite 180
Morgan Hill, California 95037

Re: K253374

Trade/Device Name:	LimiFlex® Dynamic Sagittal Tether Instrument Set
Regulation Number:	21 CFR 888.4520
Regulation Name:	Manual Instruments Designed For Use With Non-Fusion Spinous Process Tension Band Implant
Regulatory Class:	Class II
Product Code:	SGL, KCT
Dated:	May 13, 2026
Received:	May 13, 2026

Dear Mr. Fielding:

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,

STEPHANIE SMITH -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253374

Device Name
LimiFlex® Dynamic Sagittal Tether Instrument Set

Indications for Use *(Describe)*
The LimiFlex® Dynamic Sagittal Tether Instrument Set is intended to facilitate the implantation of the LimiFlex® Dynamic Sagittal Tether implant. The actual therapeutic effect is achieved by the LimiFlex® Dynamic Sagittal Tether implant.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Device Trade Name: LimiFlex® Dynamic Sagittal Tether Instrument Set

Manufacturer:
Empirical Spine
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Morgan Hill, CA, 95037 USA

Contact:
Manufacturer Contact Person
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Prepared by:
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Date Prepared: June 12th, 2026

Classifications: Manual instruments designed for use with non-fusion spinous process tension band implant; Sterilization Wrap Containers, trays, cassettes, & other accessories

Regulatory Class: II

Product Codes: SGL, KCT

Primary Predicate: K253118 Companion Spine DIAM™ Instrumentation.

Indications For Use:
The LimiFlex® Dynamic Sagittal Tether Instrument Set is intended to facilitate the implantation of the LimiFlex® Dynamic Sagittal Tether implant. The actual therapeutic effect is achieved by the LimiFlex® Dynamic Sagittal Tether implant.

Device Description:
The LimiFlex® Dynamic Sagittal Tether Instrument Set are non-implant devices that consist of instruments for use in the implantation of LimiFlex® Dynamic Sagittal Tether implants (approved via PMA P220031). These instruments are reusable, manual and non-powered surgical tools with implant specific geometry that are intended to manipulate tissue or implant materials for the positioning, alignment, placement, or removal of spinous process devices for non-fusion use.

Predicate Device:
Empirical Spine submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the LimiFlex® Dynamic Sagittal Tether Instrument Set is substantially equivalent in indications, design principles, and performance to the following predicate device, which have been determined by FDA to be Class II.

Primary Predicate: DIAM™ Instrumentation (Companion Spine, K253118).

Performance Testing Summary:
The subject instruments were validated for their intended use in a polyurethane spine model per the surgical technique. The design outputs were found to meet the customer needs. Patient contacting material (17-4PH stainless steel) is biocompatible. Additionally, the instruments demonstrated reliability and their reprocessibility via repeated simulated use testing as no corrosion or wear was observed after a total of 25 Simulated Use cycles. Further, bench testing verified that the Gen 3 Locking Driver can withstand the maximum loads expected during use.

Substantial Equivalence:
The subject device is substantially equivalent to the predicate Companion Spine DIAM™ Instrumentation in regard to intended use, operating principles and technological characteristics. Both the subject and predicate systems include manual surgical instruments and sterilization trays specifically designed for use with a non-fusion spinous process device.

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 demonstrate substantial equivalence to the predicate devices listed above.