



March 27, 2026

Lincotek Medical
% Danielle Besal
Principal Consultant
MRC Global
9085 E Mineral Circle
Suite 110
Centennial, Colorado 80112

Re: K252081

Trade/Device Name: SportLinc Syndesmosis Device
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HTN
Dated: July 2, 2025
Received: July 2, 2025

Dear Danielle Besal:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,


CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.

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

Submission Number (if known)

K252081

Device Name

SportLinc Syndesmosis Device

Indications for Use (Describe)

The Lincotek SportLinc Syndesmosis Device is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

Specifically, the Lincotek SportLinc Syndesmosis Device is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

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.

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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

| | |
|---------------------------------|---|
| Applicant Name | Lincotek Medical |
| Applicant Address | 3110 Stage Post Drive Suite 117 Bartlett TN 38133 United States |
| Applicant Contact Telephone | 574.274.0186 |
| Applicant Contact | Mr. Troy Walters |
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| Correspondent Name | MRC Global |
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| Correspondent Contact Telephone | 901.827.8670 |
| Correspondent Contact | Danielle Besal |
| Correspondent Contact Email | danielle.besal@askmrcglobal.com |

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

| | |
|---------------------|---|
| Device Trade Name | SportLinc Syndesmosis Device |
| Common Name | Single/multiple component metallic bone fixation appliances and accessories |
| Classification Name | Washer, Bolt Nut |
| Regulation Number | 888.3030 |
| Product Code(s) | HTN |

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|-------------|--|--------------|
| K043248 | TightRope Syndesmosis Device | HTN |
| K130033 | ToggleLoc System (ZipTight) | MBI |

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The SportLinc Syndesmosis Device is a sterile single-use device intended to stabilize syndesmotic trauma of the ankle. The subject implant assembly consists of UHMWPE suture tensioned between two low-profile titanium alloy buttons and is designed to complement plate fixation or to allow use as a standalone device. The button-suture assembly is assembled onto an inserter instrument and the pre-loaded assembly is packaged in a sterile single-use kit.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The Lincotek SportLinc Syndesmosis Device is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

Specifically, the Lincotek SportLinc Syndesmosis Device is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indications for use are the same as the predicate device.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The subject device has the same technological characteristics as the predicate device as it has the same basic design, is made from the same materials, and uses the identical principle of operation. Mechanical testing has demonstrated the subject device has substantially equivalent performance to that of the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

The subject device was evaluated in static and dynamic fatigue, MR compatibility (in alignment with FDA Guidance Testing and Labeling Medical Devices for Safety in the MR Environment), and biocompatibility (per FDA Guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process").

Clinical data were not applicable.

The testing demonstrated substantially equivalent performance to the predicate device.