May 14, 2025

Trax Surgical
Stephen Deane
Senior Vice President
75 Mill Street
Stoughton, Massachusetts 02072

Re: K250712
Trade/Device Name: Linkt Compression Staple System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDR
Dated: March 10, 2025
Received: March 10, 2025

Dear Stephen Deane:

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,

RYAN TROMBETTA -S

For: Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
Arthroplasty 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: 0MB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K250712

Device **Name**

Linkt Compression Staple System

Indications for Use *(Describe)*

The Linkt™ Compression Staple System is intended to be used for fracture and osteotomy fixation and joint arthrodesis of the hand and foot.

Type of Use *(Select one or both, as applicable)*

[X] 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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid 0MB number."*

# 510(k) Summary

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the Linkt Compression Staple System.

Submitted by: Trax Surgical, Inc.
75 Mill Street
Stoughton, MA 02072

Date: May 13, 2025

Contact Person: Stephen Deane
Director, Quality Assurance
781.828.4400

Proprietary Name: Linkt Compression Staple System

Common Name: Staple, Fixation, Bone

Regulation Number: 21 CFR 888.3030

Classification Name: Single / multiple component metallic bone fixation appliances and accessories,

Device Product Code, JDR

Device Class: 2

Review Panel: Orthopedic

Primary Predicate Device: Wright Medical FuseForce Flex Dynamic Compression System (K203832)

Additional Predicate Devices: Medline Unite Reflex Nitinol Staple System (K210482)
Medline Unite Reflex Nitinol Staple System (K231885)

## Device Description

The Linkt Compression Staple System consists of individually packaged, sterile, bone staple implants and a separate single use, sterile instrument set. The implants are manufactured from a nickel titanium alloy (Nitinol) which meets the requirements of ASTM F2063. The staples utilize chemical etching and passivation to form a protective oxidation layer on the outer surface. The staples are available in sizes ranging from 9mm x 9mm to 20mm x 20mm to allow the surgeon to select the appropriate device for the patient's anatomy.

The single use instruments are intended to prepare the site and deploy the staple. The instrument kit includes a drill, drill guide, locating pins and an insertion tool.

## Indication for Use

The Linkt™ Compression Staple System is intended to be used for fracture and osteotomy fixation and joint arthrodesis of the hand and foot.

## Technological Characteristics

The Linkt™ Compression Staple System, compared to the predicates, has a similar design, indications for use, and performance characteristics. The system has the same principals of operation for bone fixation. Both subject and predicate are manufactured from the same Nitinol material (ASTM F 2063) share the same serrated gripping features on the staple legs. Both the subject device and primary predicate are provided sterile by gamma irradiation.

## Performance Testing – Non-Clinical

Performance testing has demonstrated substantial equivalence to the predicates in the following areas:

- Pull out Strength Testing – ASTM F564
- Static 4 Point Bend Testing – ASTM F564
- Dynamic 4 Point Bend Testing – ASTM F564
- Corrosion Susceptibility Testing – ASTM F2129
- Radio - Frequency Induced Heating – ASTM F2182

## Performance Testing – Clinical

This section does not apply. No clinical testing was performed

## Performance Testing – Animal

This section does not apply. No animal testing was performed

## Conclusion

In accordance with 21CFR807 and based on the information provided in this premarket notification, Trax Surgical concludes that the Linkt™ Compression Staple System is substantially equivalent to the predicate devices and does not raise any new questions related to safety or effectiveness.