



January 12, 2024

LSI Solutions, Inc.
Christopher Miller
Executive Director of Regulatory Affairs and Quality
7796 Victor-Mendon Rd
Victor, New York 14564

Re: K222783

Trade/Device Name: MD Mattress Suture Placement Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Codes: GCJ, GAS
Dated: June 21, 2023
Received: June 22, 2023

Dear Christopher Miller:

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.

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,

Tek N.

Lamichhane -S

Tek N. Lamichhane, Ph.D.

Assistant Director

DHT4B: Division of Infection Control

and Plastic and Reconstructive Surgery Devices

OHT4: Office of Surgical

and Infection Control Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Digitally signed by Tek N.
Lamichhane -S
Date: 2024.01.12 17:17:45 -05'00'

Enclosure

Indications for Use

510(k) Number (if known)
K222783

Device Name
MD™ MATTRESS Suture Placement Device

Indications for Use (Describe)

The MD™ MATTRESS Suture Placement Device is indicated for use in the approximation of soft tissue and prosthetic materials.

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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510(k) Summary

Submitted By: LSI SOLUTIONS, Inc.

7796 Victor-Mendon Road

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Contact Person: Christopher B. Miller

Executive Director of Regulatory Affairs and Quality

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Date Prepared: 10 JAN 2024

Trade Name: MD™ MATTRESS Suture Placement Device

Common Name: Needle Guide

Classification Name: Endoscope and Accessories (per 21 CFR 876.1500)

Classification Regulation: 21 CFR 876.1500

Product Code: GCJ (Primary Product Code)

GAS (Secondary Product Code)

Device Classification: Class II

Predicate Device: RD180[®] - THE RUNNING DEVICE[®]
(Cleared under Premarket Notification K100593)

Device Description

The MD[™] MATTRESS Device is a nonpowered, hand-operated suture placement device that facilitates placement of a stitch, for example horizontal mattress stitches. Each sterile package contains one single-patient-use MD[™] MATTRESS Device. The lavender device tip has an integrated tissue jaw incorporating a jaw width indicator that identifies the jaw when it is embedded in tissue. Two curved needles emerge from their protective compartments to advance across the tissue jaw, rotating about the circular needle axle indicator to engage needle caps with attached suture that are loaded into specialized needle cap compartments. An angulation indicator on the tip and the device shaft depicts the direction of the device tip angle, which is adjusted using the white angulation knob. The embossed arrow and word “IN” indicate the direction the device tip moves when the angulation knob is rotated clockwise; the device tip can be angled up to approximately 15° in either direction, as indicated by the 3 embossed radial lines in the angulation indicator. The lavender rotational knob can be rotated to orient the device shaft and tip into one of six distinct positions. The rotational knob has an integrated eyelet, for stabilizing a suture tube with indwelling suture, and an indicator fin that is aligned with the device tip tissue jaw. Fully squeezing the lavender lever toward the white handle causes both curved needles in the device tip to advance across the tissue jaw toward the needle cap compartments. Fully releasing the lever causes both needles and their engaged needle caps with

attached suture to retract back across the tissue gap, pulling both suture ends through the targeted tissue within the jaw. Fully squeezing the lever again causes the needles and engaged needle caps with attached suture to advance back into their corresponding needle cap compartments, and an internal mechanism alternates the device into its rearming mode. Fully releasing the lever again causes the needles to retract into their protective compartments, leaving the needle caps and attached suture ends in the needle cap compartments. Subsequently squeezing and releasing the lever will repeat the pickup and rearm cycle.

While the MD™ MATTRESS Device is used for the placement of MD™ QUICK LOAD® SURGICAL SUTURES, this premarket submission does not include a request for clearance of suture materials since MD™ QUICK LOAD® SURGICAL SUTURE is listed on FDA's Establishment Registration and Device Listing database (K203081).

One (1) MD™ MATTRESS Device is provided per package, and the MD™ MATTRESS Device is intended to facilitate the placement of multiple sutures through tissue and prosthetic materials.

Intended Use

The MD™ MATTRESS Device is intended for use in the approximation of soft tissue and prosthetic materials.

Indications for Use

The MD™ MATTRESS Suture Placement Device is indicated for use in the approximation of soft tissue and prosthetic materials.

Technological characteristics (comparison to Predicate Device)

Both the predicate RD180[®] Device and the subject MD[™] MATTRESS Device have the same intended use: “Intended for use in the approximation of soft tissue and prosthetic materials.” The predicate RD180[®] Device is “indicated for use in the approximation of soft tissue and prosthetic materials,” and LSI recommends its use with 2-0 polyester suture, among other suture types. The subject MD[™] MATTRESS Device has similar indications. The MD[™] MATTRESS Device is “indicated for use in the approximation of soft tissue and prosthetic materials.” The subject and predicate devices are both designed for sewing suture on similar technical principles. Both devices are single-patient-use, nonpowered, hand-operated devices that incorporate a lever-driven mechanism that pierces needles through tissue, picks up suture, and pulls the suture back through the tissue to facilitate placing a stitch.

Both the subject and predicate devices operate on the same principle to accomplish the tasks the devices are intended to perform. These tasks include: loading suture needle caps into the device tip; passing the device tip through the surgical access site (optionally through a cannula if appropriate); selecting the desired device tip position over a target site; firing needles through tissue and pulling the suture back through the tissue; rearming the device to allow for placement of additional tissue bites (as deemed appropriate by the surgeon); and removing the suture needle caps from the needles. Both the subject and predicate devices are provided sterile, after sterilization with ethylene oxide such that a minimum lethality of 10^{-6} is achieved. The predicate RD180[®] Device is a stainless steel and polymer suture delivery device. The MD[™] MATTRESS Device is made from similar, often identical, materials. Both devices conform to the requirements of ISO 10993. The predicate device is packaged in a rigid thermoformed PETG

blister tray with a Tyvek® cover. The subject device is packaged in the similar configuration with similar materials: a blue-tint PETG tray and retainer inserted into a Tyvek®/Nylon pouch.

The MD™ MATTRESS Device and the predicate RD180® Device are substantially equivalent. The subject and predicate devices are comparable, and the differences do not introduce any new risks, and have no negative impact on the safety and efficacy of the MD™ MATTRESS Device.

A summary of the comparison between the subject MD™ MATTRESS Device and predicate RD180® Device is provided in the table below.

Table 6: Substantial Equivalence Comparison			
Subject Area	Predicate Device: RD180® - THE RUNNING DEVICE®		Subject Device: MD™ MATTRESS Device
510(k) Number:	K100593	N/A	K222783
Device Class:	II	SAME	II
Classification Regulation:	21 CFR 876.1500	SAME	21 CFR 876.1500
Product Code:	G CJ	SAME	G CJ
Intended Use:	Intended for use in the approximation of soft tissue and prosthetic materials.	SAME	Intended for use in the approximation of soft tissue and prosthetic materials.
Indications for Use:	Indicated for use in the approximation of soft tissue and prosthetic materials.	SAME	Indicated for use in the approximation of soft tissue and prosthetic materials.

Table 6: Substantial Equivalence Comparison

Subject Area	Predicate Device: RD180® - THE RUNNING DEVICE®		Subject Device: MD™ MATTRESS Device
Single Use/ Reusable:	Single Use	SAME	Single Use
Design:	Device tip (including a tissue jaw, single straight needle, and a needle cap compartment)	COMPARABLE	Device tip (including a tissue jaw, jaw width indicator, dual curved needles, needle axle indicator, needle cap compartments, and an angulation indicator)
	Device shaft	COMPARABLE	Device shaft (including an angulation knob, rotational knob with an integrated eyelet and indicator fin)
	Pink lever	COMPARABLE	Lavender lever
	White handle	SAME	White handle

Table 6: Substantial Equivalence Comparison

Subject Area	Predicate Device: RD180® - THE RUNNING DEVICE®		Subject Device: MD™ MATTRESS Device
Technological Characteristics:	<p>Nonpowered, hand-operated; incorporating a lever-driven mechanism utilizing needle-and-needle-cap technology to place suture through tissue or prosthetic materials using a single straight needle.</p> <p>The predicate device does not contain any articulation or rotational knobs or functions.</p>	COMPARABLE	<p>Nonpowered, hand-operated; incorporating a lever-driven mechanism utilizing needle-and-needle-cap technology to place suture through tissue or prosthetic materials using dual curved needles.</p> <p>The subject device contains an articulation knob, which can be used to angulate the device tip inward or outward, and a rotational knob, which enables the device shaft and correspondingly the device tip to rotate through six distinct positions.</p>
Target Population:	Any patient requiring the approximation of soft tissue or prosthetic materials.	SAME	Any patient requiring the approximation of soft tissue or prosthetic materials.

Table 6: Substantial Equivalence Comparison			
Subject Area	Predicate Device: RD180® - THE RUNNING DEVICE®		Subject Device: MD™ MATTRESS Device
Environment of Use:	<p>Suitable for use in any environment where surgical procedures occur under the supervision of a physician.</p> <p>Compatible with open surgeries, smaller access/minimally invasive surgeries, and surgery through a cannula or other access ports with seals to maintain positive CO₂ pressure at the surgical site.</p>	SAME	<p>Suitable for use in any environment where surgical procedures occur under the supervision of a physician.</p> <p>Compatible with open surgeries, smaller access/minimally invasive surgeries, and surgery through a cannula or other access ports with seals to maintain positive CO₂ pressure at the surgical site.</p>
Sterility	To be sterilized with ethylene oxide such that a minimum lethality of 10 ⁻⁶ is achieved.	SAME	To be sterilized with ethylene oxide such that a minimum lethality of 10 ⁻⁶ is achieved.
Materials and Biocompatibility	<p>Comprising stainless steel and polymers.</p> <p>Conforms to the requirements of ISO 10993-1:2009.</p>	COMPARABLE	<p>Comprising stainless steel and polymers.</p> <p>Conforms to the requirements of ISO 10993-1:2018.</p>
Packaging	Packaged in a rigid thermoformed PETG tray with a Tyvek® cover.	COMPARABLE	Packaged in a PETG tray and retainer lid which are sealed in a Tyvek®/Nylon pouch.

Performance Testing Summary

Bench top performance testing was conducted to verify that the MD™ MATTRESS Device will perform as intended and to ensure the device will perform equivalently to the predicate device.

The following non-clinical tests were conducted, and all results met the performance and risk-based acceptance criteria:

- Functional Design Verification and Validation Testing to ensure the Design Input Requirements were met.
- Biocompatibility per ISO 10993-1:2018 and in accordance with FDA Guidance for Industry *Use of International Standard ISO 10993-1, "Biological evaluation of medical device – Part 1: Evaluation and testing within a risk management process, September 4, 2020*. The MD™ MATTRESS Device can be classified as an externally communicating medical device that has limited contact (≤ 24 hours) with tissue. The battery of testing included:
 - Chemical characterization
 - Cytotoxicity
 - Sensitization
 - Irritation
 - Material-mediated pyrogenicity
 - Acute systemic toxicity
- Packaging/Shelf-life Testing per ISO 11607-1:2019 demonstrating a 2 year shelf life.

Clinical Testing

Not applicable. Neither the predicate nor the subject product require clinical testing. The substantial performance testing discussed above confirms the reliability and excellent performance of the MD™ MATTRESS Device. The performance testing included multiple experiments that do not require clinical testing in patients.

Substantial Equivalence

The subject device and predicate device have the same intended use and technological characteristics. Non-clinical performance data has demonstrated the subject device is substantially equivalent to the predicate device.

Conclusion

The subject MD™ MATTRESS Device is substantially equivalent to the predicate RD180® Device, submitted under Premarket Notification K100593 and cleared in 2010. Extensive testing demonstrates that the proposed product consistently provides excellent suture placement and can be dependably manufactured. The MD™ MATTRESS Device will be safe and effective for the approximation of soft tissue and prosthetic materials.