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Premarket Notification

510(k) Summary of Safety and Effectiveness Information

DATE OF SUMMARY PREPARATION

July 10, 1996

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PROPRIETARY NAME

MedicineLodge, Inc. (MLI) Modular Staple

COMMON NAMES

Orthopedic Bone Staple
Orthopedic Washer

CLASSIFICATION NAME

Fixation Bone Staple

CLASSIFICATION REFERENCE

21 CFR § 888.3030

DEVICE PRODUCT CODE

87 JDR

CLASSIFICATION PANEL

Orthopedic and Rehabilitation Devices

PROPOSED REGULATORY CLASS

In accordance with FDA classification of bone staples and orthopedic washers as Class II medical devices, this device is proposed for placement in Class II.

REASON FOR PREMARKET NOTIFICATION

The MLI Modular Staple is a new medical device proposed for placement in Class II.

SPECIAL CONTROLS

At this time, Food and Drug Administration generated Performance Standards applicable to MedicineLodge, Inc. Modular Staple are not in force. MedicineLodge, Inc. does not believe that device testing is necessary to demonstrate the substantial equivalence of the device. MedicineLodge, Inc. utilizes materials and vendor certifications, in-house standard operating procedures (SOP's), and applicable ASTM standards, as appropriate in the manufacture of the device.

DEVICE DESCRIPTION

MedicineLodge, Inc. (MLI) Modular Staples are indicated for use in soft tissue graft fixations to the femur or tibia, or both, during cruciate ligament, tendon or other soft tissue graft (e.g. semitendinosus) repair procedures.

The MLI Modular Staple is a three piece device consisting of a staple, a washer and a set screw that are designed to be used as an assembly unit. Each of the implant components are manufactured from Ti-6Al-4V ELI, per ASTM F-136 and are discussed in turn below.

SUBSTANTIAL EQUIVALENCE COMPARISON

Based on the design concept, indications for use, use of standard materials, and feature comparisons to selected predicate devices, MedicineLodge, Inc. believes that sufficient evidence exists to conclude that the MLI Modular Staple is substantially equivalent to existing legally marketed soft tissue bone staples.

Table 1 at the end of this section summarizes all relevant feature comparisons between the MLI Modular Staple and the selected predicate devices.

To begin, the general design concept, methods of sterilization, and device packaging for all MLI Modular Staple components are equivalent to those used for the selected predicate devices.

MedicineLodge, Inc. also uses materials (Ti-6Al-4V per ASTM F-136) and manufacturing methods equivalent to those used for the production of the Linvatec, Inc. Concept Staple Fixation System. However, it should be mentioned that Richards Fixation Staples are instead manufactured from Cobalt-Chromium (per ASTM F-75) and the devices are cast rather than machined. MedicineLodge, Inc. believes that the use of proven implant materials and manufacturing methods relative to one of the selected predicate devices establishes the substantial equivalence of the device in this regard.

MLI Modular Staples are indicated for use in soft tissue graft fixations to the femur or tibia, or both, during cruciate ligament, tendon or other soft tissue graft (e.g. semitendinosus) repair procedures. The previously listed predicate device systems are similarly indicated for procedures involving soft tissue reconstruction. In fact, the Richards Fixation Staples have indications for use far broader in scope.

The MLI Modular Staple is designed to be used as an assembly unit. The use of screws and washers in soft tissue reconstruction is well established. The modular design of the MLI Modular Staple utilizes known screw and washer technology in combination with a standard bone staple design. The two legs of the staple serve to anchor the implant and soft tissue graft to the bone, while the washer and set screw act as an additional means of affixing the soft tissue graft to bone. In cases where the surgeon uses the staple assembly with the set screw alone, the assembled device is identical to a standard bone staple with an elongated spike extending from the center of the staple base.

The staples are designed in accordance with *ASTM F-564: Standard Specification for Bone Staples* and are thus similar in two-legged design to many currently marketed bone staple devices. The staples are provided in the sizes tabulated below:

MLI Staple Width	MLI Staple Length
13 mm 16 mm 20 mm	25.4 mm

For each of the three staple designs, a washer has been designed to uniquely fit the staple. Each washer is designed to be compatible with a single staple size and the device labeling will clearly indicate that the packaged washer is for use with only the specified size of staple. The MLI Modular Staple Washers are offered in the sizes indicated in the table below.

Washer Size	For Use With:
13 mm	13 mm Modular Staple
16 mm	16 mm Modular Staple
20 mm	20 mm Modular Staple

The washers possess spikes spaced equidistant from each other on the distal side of the washer to penetrate the soft tissue graft, thus anchoring the graft between the bone and the distal surface of the washer.

The washers have a central hole smaller in diameter than the threaded portion of the set screw. This ensures that only the spike at the tip of the set screw passes through the central hole in the washer component. This provides a means for the set screw to apply a compressive force to the washer as the screw is threaded into the staple base. In this manner, the washer is more firmly pressed onto the soft tissue graft thus increasing the compression on the graft.

The MLI Modular Staple Set Screw is a small, spiked screw designed to be inserted into the threaded hole of the staple. The spike at the tip of the screw is designed to pass through the staple and washer to penetrate the soft tissue graft.

The screw is designed to be inserted using a standard 3.5 mm hex driver (per ASTM F-116). Both the threaded portion of the set screw and the hexagonal head drive connection conform to ISO 5835, *Metal Bone Screws with Hexagonal Drive Connection, Spherical Under-Surface of Head, Assymetrical Thread Dimensions* and ISO 9268, *Metal Bone Screws with Conical Under Surface of Head, Symmetrical Thread Dimensions*. In this respect, the set screw is equivalent in thread design and hexagonal head drive geometry to standard bone screws.

As described previously, the threaded portion of the screw is designed to thread into the central threaded hole of the staple component. As the screw is threaded into the staple, the spike is forced through the staple and washer and into the soft tissue graft. This mechanism potentially serves to more firmly secure the soft tissue graft between the implant and the host bone.

DEVICE TESTING

As described previously, MLI Modular Staples are manufactured from proven materials and are equivalent in design to the selected predicate devices. The staple design is virtually identical to standard bone staple design (per ASTM F-564) and the set screw thread and hexagonal head drive design is in accordance with applicable ISO standards (ISO 5835, ISO 9268). Also, the washers are designed to uniquely fit the staples and the device labeling clearly states that the packaged washer is only to be used with the indicated staple size.

For these reasons, MedicineLodge, Inc. does not believe that device testing is necessary to demonstrate the substantial equivalence of the device. MedicineLodge, Inc. does plan to perform future device testing according to appropriate ASTM standards to quantitatively compare the performance of the MLI Modular Staple device to other commercially available bone staples in simulated testing.

TABLE 1

Feature comparisons between the MedicineLodge, Inc. Modular Staple and the selected predicate devices (differences are indicated in **bold** print).

	MLI Modular Staples	Richards Fixation Staples	Linvatec Concept Staple Fixation System
Indications	MedicineLodge, Inc. Modular Staples are indicated for use in soft tissue graft fixations to the femur or tibia, or both, during cruciate ligament, tendon or other soft tissue graft (e.g. semitendinosus) repair procedures.	1. Tendon repairs, transfers or transplants such as in the treatment of paralytic conditions, tendon avulsions or ruptures, in which the tendon is fixed to bone using either a table staple or two regular fixation staples. 2. Ligament repairs, reconstruction or replacement in which the ligament is fixed to bone as in Number 1 above. 3. Adjunctive internal fixation of fractures, arthrodeses such as triple arthrodesis. 4. The fixation of avulsed fragments to bone such as the greater humeral or femoral tuberosity, the calcaneum, the tibial tubercle, or other such injuries.	The Linvatec Staple Fixation System is used as a means of attaching soft tissue to bone.
Materials	**Ti6Al4V ELI (per ASTM F-136)**	**Cobalt Chromium (per ASTM F-75)**	**Ti6Al4V ELI (per ASTM F-136)**
ASTM F-564 Conformance	Yes	Yes	Yes
Staple Plate Profile	Low	Low	Low
Staple Widths	**13, 16, 20 mm**	**6.35, 7.9, 11.1, 14.3 mm**	**9.5, 13.5, 16.5 mm**
Staple Lengths	**25.4 mm**	**unknown**	**22-23 mm**
Leg Geometry	Barbed	Barbed	Barbed
Optional Washer	Yes	No	No
Central Set Screw	Yes	No	No
Number of Components	Three	One	One
Method of Insertion	Staple Inserter	Staple Inserter	Staple Inserter
Option to exert further pressure on the graft after staple insertion	Yes	No	No
Surface Texture	Satin Finish	Satin Finish	Satin Finish
Spikes on Distal Surface of Staple	Yes	Yes	Yes
Sterilization Status	Sterile & Non-sterile	**Sterile & Non-sterile**	Sterile & Non-sterile
Manufacturer	MedicineLodge, Inc.	**Smith & Nephew Richards, Inc.**	Linvatec, Inc.
510(k) Approved?	N/A	**Presumed Preamendment**	Yes - K894929