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Premarket Notification
510(k) Summary of Safety and
Effectiveness Information

DATE OF SUMMARY PREPARATION

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PROPRIETARY NAME

MedicineLodge, Inc. (MLI) Soft Tissue Screw and Washer System

COMMON NAMES

Orthopedic Bone Screw
Orthopedic Washer

CLASSIFICATION NAME

Non-degradable Soft Tissue Fastener

CLASSIFICATION REFERENCE

Currently, no FDA classification exists for Non-degradable Soft Tissue Fasteners

DEVICE PRODUCT CODE

MBI

CLASSIFICATION PANEL

Orthopedic and Rehabilitation Devices

PROPOSED REGULATORY CLASS

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

REASON FOR PREMARKET NOTIFICATION

The MLI Soft Tissue Screw and Washer System 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. Soft Tissue Screws and Washers are not in force. However, MedicineLodge, Inc. has conducted mechanical testing on four screw/washer configurations to demonstrate the substantial equivalence of the device. Additionally, MedicineLodge, Inc. utilizes materials and vendor certifications, in-house standard operating procedures (SOP's), and ASTM standards, as appropriate.

INDICATIONS FOR USE

MedicineLodge, Inc. soft tissue anchoring bone screws and washers 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.

SUBSTANTIALLY EQUIVALENT PREDICATE DEVICES

MedicineLodge, Inc. believes that several commercially available devices are substantially equivalent to the MLI Soft Tissue Screw and Washer System. Within the proposed class, the following devices are used as predicate devices for comparison:

- 1) **Linvatec Concept Soft Tissue Anchoring Implants**
Linvatec, Inc.; Largo, FL
- 2) **Arthrotek Ligament Screw System**
Arthrotek, Inc., Ontario, CA
- 3) **Mitek Screws and Washers**
Mitek Surgical Products, Inc.; Norwood, MA

MedicineLodge, Inc. believes that the information presented below demonstrates the substantial equivalence of the MLI Soft Tissue Screw and Washer System when compared to the above selected predicate devices.

SUBSTANTIAL EQUIVALENCE COMPARISON

To begin, the materials, method of manufacture, method of sterilization, and device packaging for all MLI Soft Tissue Screw and Washer System components are equivalent to those used for the selected predicate devices.

MLI Soft Tissue Screws and Washers 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.

The MLI Soft Tissue Screws and Washers are designed to be used as an assembly unit. The MLI Soft Tissue Anchoring Screws are provided in standard sizes, as tabulated below:

Screw Diameter	Screw Length
4.5 mm (Cortical)	30 mm - 60 mm, in 2 mm increments
6.5 mm (Cancellous)	20 mm - 55 mm, in 5 mm increments

MLI Screws are equivalent in design to currently marketed standard bone screws, with all threads and defining screw features conforming to ISO 5835, *Metal Bone Screws with Hexagonal Drive Connection, Spherical Under-Surface of Head, Assymetrical Thread Dimensions*. The screws are self-tapping and are designed to be manually inserted using a standard 3.5 mm hex driver. Engineering Drawings are provided in Exhibit I for reference.

The MLI Washers are designed to be universally compatible with both the 4.5 mm and 6.5 mm MLI Screws and are provided in the three following design configurations to allow the surgeon a variety of washers to choose from:

Washer Shape	Washer Diameter
Round	14 mm, 17 mm, 20 mm
Triangular	17.5 mm, 20.5 mm
Oval	19 mm, 22 mm

The washers possess spikes spaced equidistant from each other on the distal side of the washer to penetrate the host bone and thus anchor the graft in place. Engineering drawings of the washers are also provided in Exhibit I for reference.

Although the washer design configurations listed above may vary slightly from standard washers used in soft tissue repair, testing performed by MedicineLodge, Inc. shows that these differences do not compromise the performance of the washers relative to standard round washers in their intended clinical use. This testing is discussed below.

DEVICE TESTING

MedicineLodge, Inc. has conducted device testing on a variety of screw/washer configurations to assess the performance of the MLI Soft Tissue Screw and Washer

System. These results were then used compare the performance of the MLI Screws and Washers to a commercially marketed soft tissue screw and washer system.

The following tests were conducted using the indicated screw/washer combinations:

- (i) Test #1: Fixation strength of the MLI 4.5mm X 52mm Cortical Screw and MLI-Small Round Washer (13 mm) in Static Bone Patellar Tendon Tensile Testing in a Bass Wood Model.
- (ii) Test #2: Fixation strength of the MLI 4.5mm X 52mm Cortical Screw and MLI-Large Round Washer (18 mm) in Static Bone Patellar Tendon Tensile Testing in a Bass Wood Model.
- (iii) Test #3: Fixation strength of the MLI 4.5mm X 52mm Cortical Screw and MLI-Triangular Washer (11.5 mm) in Static Bone Patellar Tendon Tensile Testing in a Bass Wood Model.
- (iv) Test #4: Fixation strength of the MLI 4.5mm X 52mm Cortical Screw and MLI-Football Washer (11.5 mm x 8.5 mm) in Static Bone Patellar Tendon Tensile Testing in a Bass Wood Model.

The mode of failure for all MLI Screw and Washer configurations was similar for all screw/washer constructs tested, wherein the ligament pulled out from under the washer. The modes of failure are also consistent with results obtained by Matthews et.al and Kurosaka et.al where the site of failure was at the point of ligament anchorage to the implant. It is important to note that yield of the graft construct results in permanent deformation of the ligament, which can in turn result in a loose or lax graft. For this reason, MedicineLodge, Inc. believes that the yield load data best measures the observed mode of failure.

When the yield load results for the various MLI Soft Tissue Screw and Washer System screw/washer constructs were compared to the currently marketed screw/washer construct, the MLI screw/washer constructs all performed as well or better than the predicate screw/washer construct.

It is important to state that the washer sizes that will comprise the MLI Soft Tissue Screw and Washer System will be larger than those tested. This thus increases the distal surface area of the washers, which in turn should result in increased fixation strength of the graft construct in true clinical application of the product. In particular, for the Football washer (tested size: 11.5mm; marketed sizes: 19mm and 22mm), this size increase should provide additional assurance that the device will perform equivalent to the predicate screw/washer construct.

It is our belief that these results confirm the equivalence of the MLI Soft Tissue Screw and Washer System relative to the tested predicate device in testing devised to simulate clinical application of the product.

CONCLUSION

Based on the design concept, indications for use, use of standard materials, and feature comparisons to the selected predicate devices, MedicineLodge, Inc. believes that sufficient evidence exists to conclude that MLI Soft Tissue Screw and Washer System is

substantially equivalent to existing legally marketed soft tissue anchor screw and washer systems.

Table 1 on the following page summarizes the relevant feature comparisons between the MLI Soft Tissue Screw and Washer System and the selected predicate devices.

TABLE 1

Feature comparisons between the MedicineLodge, Inc. Soft Tissue Anchoring Screw and Washer System and a selected predicate device system (differences are indicated in **bold print**).

	MLI Soft Tissue Screw and Washer System	Mitek Screws and Washers	Linvatec Concept Soft Tissue Anchoring Set	Arthrotek Ligament Screw and Washer System
Indications	MedicineLodge, Inc. soft tissue screws and washers 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.	Mitek screws and washers are used to attach ligaments, tendons and other soft tissue to bone.	Concept soft tissue screws and washers are used to attach ligaments, tendons and other soft tissue to bone.	Arthrotek Ligament Screw and Washer system is designed to produce an efficient surgical procedure for iliotibial tenodesis in anterior cruciate reconstruction.
Materials	Ti6Al4V ELI (per ASTM F-316)	Ti6Al4V ELI (per ASTM F-316)	Ti6Al4V ELI (per ASTM F-316)	Ti6Al4V ELI (per ASTM F-316)
Cortical Screws	<i>Length:</i> 30 mm to 60 mm, in 2 mm increments <i>Outer Diameter:</i> 4.5 mm	<i>Length:</i> 26 mm to 76 mm, in 2 mm increments <i>Outer Diameter:</i> 4.5 mm	<i>Length:</i> 30 mm to 45 mm, in 5 mm increments; 50 mm to 70 mm with smooth proximal shank, in 10 mm increments. <i>Outer Diameter:</i> 3.5 mm	<i>Length:</i> 30 mm to 80 mm, in 2 mm increments <i>Outer Diameter:</i> 4.5 mm
Cancellous Screws	<i>Length:</i> 20 mm to 55 mm, in 5 mm increments <i>Outer Diameter:</i> 6.5 mm	<i>Length:</i> 20 mm to 50 mm, in 5 mm increments <i>Outer Diameter:</i> 6.5 mm	Not Listed	<i>Length:</i> 25 mm to 55 mm, in 5 mm increments <i>Outer Diameter:</i> 6.5 mm
ISO Conformance of Screw Design	Yes	Yes	Yes	Yes
Screw Head Profile	Low profile	Low Profile	Low Profile	Low Profile
Surface Finish	Satin Texture	Satin Texture	Satin Texture	Satin Texture
Tapped/Self-tapping	Self-tapping	Self-tapping	Self-tapping	Tapped hole
Method of Insertion	3.5mm Hex Driver	2.5mm Hex Driver	3.5mm Hex Driver	2.5mm Hex Driver
Washers	Round: 14mm, 17mm, 20mm Triangular (Delta): 17.5mm, 20.5mm Oval (Football): 19mm, 22mm	Round: 14mm, 17mm, 20mm	Round (with post): 14mm, 17mm, 20mm Round (Flat Washers): 14mm, 17mm	Round: 14mm, 18mm
Suture Holes in Washer	No	No	Yes	Yes
Imbrications on Distal Surface of Washer	Yes	Yes	No	No
Sterilization Status	Sterile & Non-sterile	Sterile & Non-sterile	Sterile & Non-sterile	Sterile & Non-sterile
Manufacturer	MedicineLodge, Inc.	Mitek Surgical Products, Inc.	Linvatec, Inc.	Arthrotek, Inc.
Currently Marketed? (Presumed 510(k) Approved)	N/A	Yes	Yes	Yes