

13. 510 (K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION**13.1 Date of Summary Preparation**

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13.2 Manufactures Contact Person

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13.3 Proprietary Device Name

MLI - Cross Pin

13.4 Common Name

Threaded Fixation Pin

13.5 Classification Name

Smooth or Threaded Metallic Bone Fixation Fastener

13.6 Classification Reference

21CFR 888.3040

13.7 Device Product Code

87 JDW

13.8 Regulatory Class

Class II

13.9 Special Controls

At this time, the Food and Drug Administration generated performance standards applicable to the MLI - Cross Pin are not in force.

13.10 Materials

The following material is used in the manufacturing of the MLI - Cross Pin (All Sizes).
Ti-6Al-4V ELI per ASTM F-136.

13.11 Indications for Use

The MedicineLodge, Inc. (MLI) - Cross Pin is used to secure soft tissue graft fixations during cruciate ligament reconstruction surgeries.

13.12 Device Description

The MedicineLodge, Inc. (MLI) Cross Pin is a partially threaded metal fixation fastener used to attach soft tissue allografts or autografts to host bone.

To begin, the device is similar in design to currently marketed threaded fixation pins. The spiral threads (per ISO 5835) on the proximal one-third of the screw are designed to firmly grasp the host bone during insertion. The distal two-thirds of the MLI Cross Pin possesses two design characteristics common to cross pin devices.

- a. Unthreaded Distal Two-thirds: The absence of threads along this portion of the cross pin allows the passage of the soft tissue graft around the screw.
- b. Tapered Distal Two-thirds: The taper of the cross pin along the distal two-thirds allow for easy passage and positioning of this portion of the device through the tibio-femoral tunnel.

The MLI Cross Pin head conforms to ISO 5835 and the device is designed to be manually inserted using a standard cannulated 3.5mm (cannulation of 0.046") hex driver, per ASTM F-116-85.

The MLI Cross Pin will be provided with a 6.5mm outer diameter (Per ISO 5835) offered in lengths of 40mm, 50mm, 60mm and 70mm lengths. Table below lists the various MLI Cross Pin combinations along with corresponding part numbers.

All MLI Cross Pins will be manufactured from Ti-6Al-4V ELI material (ASTM F-136) and are anodized per AMS 2488C for a smoother and more uniform surface finish. The anodized layer additionally provides an inert coating which helps to prevent galling and corrosion by providing a passive surface.

As mentioned previously, the MLI Cross Pin possesses a central cannulation to allow the use of guide wires for accurate placement of the device in the host bone. In application, the use of guide wires reduces the chances of tunnel screw divergence. All MLI Cross Pins are designed for use with a 0.042 inch diameter guide wire, which is also provided by MedicineLodge, Inc. All instrumentation designed for use with the MLI Cross Pin is defined in Section 6, with engineering drawings presented in Appendix B.

MLI- Cross Pin Sizes

PART # STERILE	PART # NON-STERILE	DIAMETER (MM)	LENGTH (MM)	DESCRIPTION
706540	716540	6.5mm	40mm	6.5mm x 40mm Cross Pin
706550	716550	6.5mm	50mm	6.5mm x 50mm Cross Pin
706560	716560	6.5mm	60mm	6.5mm x 60mm Cross Pin
706570	710570	6.5mm	70mm	6.5mm x 70mm Cross Pin

13.13 Substantially Equivalent Predicate Devices

Predicate Device Description

NO.	MANUFACTURE'S NAME	DEVICE NAME	510 (K) APPROVED
1.	DePuy, Inc. Warsaw, IN	DePuy Cross Pin Screw System	Yes
2.	Arthrex, Inc. Naples, FL	Arthrex Cross Pin	Yes

13.14 Substantial Equivalence Comparison

The following table displays the similarities and differences of the new device to the legally marketed devices to which equivalency is claimed. The materials, method of manufacture, method of sterilization and device packaging are identical to the predicate devices.

Direct Comparison to Already Marketed Products

NO.	FEATURE	MLI - CROSS PIN	DEPUY CROSS PIN
1.	Intended Use	Cruciate Ligament Reconstruction Surgery	Cruciate Ligament Reconstruction Surgery
2.	Diameter	6.5mm	4.5mm
3.	Lengths	40mm, 50mm, 60mm and 70mm	40mm 45mm, 50mm, 55mm, 60mm, 65mm and 70mm
4.	Material	Ti-6Al-4V ELI per ASTM F-136	316 LVM SS
5.	Method of insertion	3.5mm Hex	4.0mm Hex
6.	Method of fixation to bone	Screw Threads	Screw Threads
7.	Self tapping feature	Yes	Yes
8.	Method of graft attachment	Loop soft tissue around implant	Loop soft tissue around implant or drill hole through bone end of graft
9.	Cannulation for guide wire	.046 cannulation for use of .042 guide wire	None
10.	Surface finish	Ti anodized	High polish
11.	Thread crest	Soft	Soft
12.	Packaging	Sterile and Non-Sterile	Sterile and Non-Sterile

13.15 Performance Testing (Subject and Predicate Devices)

MedicineLodge, Inc. has conducted mechanical testing on the subject and a predicate device (DePuy Cross Pin; DePuy, Inc., Warsaw, IN) to prove substantial equivalence. The following mechanical tests were performed.

- a. Static bending properties of the DePuy Cross Pin in a 3-point bending situation.
- b. Static bending properties of the MLI - Cross Pins in a 3-point bending situation.

MedicineLodge, Inc. conducted bending property studies on the subject and predicate device in a non-in-vitro mode to determine the effect of using a load on the cross pin to simulate the load applied on the cross pin via a graft.

Students t-test were done to determine any statistical differences or similarities between the two types of cross pin ligament fixation devices.

In comparing the load to failure between the two cross pin designs, we find no significant differences ($p > 0.05$).

Based on the mechanical testing conducted by MedicineLodge, Inc. on the subject and predicate device, conclusions can be drawn regarding the design difference between the subject and predicate device. The design differences seen in the subject device offer no inherent weakness and have functioned similar to the predicate device often showing potential for improved performance. MedicineLodge, Inc. would like to claim substantial equivalence to the DePuy Cross Pin which is commercially available in the U.S. market.

13.16 Differences from Predicate Devices

The following enumerates the differences in design between the MLI - Cross Pin in comparison with a selected predicate device.

- a. Material: The MLI - Cross Pin is manufactured from Ti-6Al-4V ELI per ASTM F-136 where as the DePuy Cross Pin is manufactured from 316 LVM stainless steel per ASTM A-479/A-479M.
- b. Cannulated vs. Non-cannulated: The MLI - Cross Pin design allows for the use of a .042" guide wire to help position the cross pin in the tunnel. The DePuy Cross Pin features no such cannulation.
- c. 6.5mm vs 4.5mm thread form: The MLI - Cross Pin thread form is that of a 6.5 HB (ISO 5835). The DePuy Cross Pin thread form is that of 4.5 HB (ISO 5835).
- d. Screw head vs no head: The MLI - Cross Pin has a screw head (ISO 5835) to accommodate a standard 3.5mm hex to accommodate a hex driver (ASTM F-136). The DePuy Cross Pin has no defined screw head but has a hex nut used in conjunction with a hex driver socket.

13.17 Conclusion

Based on the design concept, use of standard material, feature comparisons to selected predicate devices, the device and predicate device testing, MedicineLodge, Inc. believes that sufficient evidence exists to conclude that the MLI - Cross Pin is substantially equivalent to existing legally marketed endosteal cruciate fixation devices.