13. 510 (K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION K961905

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 - Set Screw

13.4 Common Name
Endosteal Set Screw

13.5 Classification Name
Smooth or Threaded Metallic Bone Fixation Fastener

13.6 Classification Reference
21CFR 888.3040

13.7 Device Product Code
87 HWC

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 - Set Screw are not in force.

13.10 Materials
The following material is used in the manufacturing of the MLI - Set Screw.
Ti-6Al-4V ELI per ASTM F-136.

13.11 Indications for Use
The MedicineLodge, Inc. (MLI) - Set Screw is used to secure graft fixations during cruciate ligament, tendon or other soft tissue reconstruction surgeries.

13.12 Device Description

The MedicineLodge, Inc. (MLI) Set Screw is a threaded, cannulated bone screw used to attach bone-tendon-bone allografts or autografts to host bone.

To begin, the design is similar in design to currently marketed endosteal set screws. The spiral threads are designed to firmly grasp the bone and graft during screw insertions, and the tapered proximal nose allows the set screw to hold the bone end of the graft upon insertion of the set screw. MLI Set Screws are designed to be manually inserted using a standard cannulated 3.5mm (cannulation of 0.096") hex driver, per ASTM F-116-85.

The MLI Set Screw will be available in 9mm and 11mm outer diameters, each offered in lengths of 20mm, 25mm, 30mm, 35mm and 40mm. The table below lists the various set screw combinations along with corresponding part numbers.

All MLI Set Screws are 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 Set Screw possesses a central cannulation to allow the use of guide wires for accurate placement of the screw in the host bone. In application, the use of guide wires reduces the chances of tunnel screw divergence. All MLI Set Screws are designed for use with a 0.093 inch diameter guide wire, which is also provided by MedicineLodge, Inc.

TABLE
MLI - Set Screw Sizes

PART # STERILE	PART # NON-STERILE	MLI - DIAMETER	LENGTH	DESCRIPTION
730920	740920	9mm	20mm	9mm x 20mm Set Screw
730925	740920	9mm	25mm	9mm x 25mm Set Screw
730930	740930	9mm	30mm	9mm x 30mm Set Screw
730935	740935	9mm	35mm	9mm x 35mm Set Screw
730940	740940	9mm	40mm	9mm x 40mm Set Screw
731120	741120	11mm	20mm	11mm x 20mm Set Screw
731125	741125	11mm	25mm	11mm x 25mm Set Screw

PART # STERILE	PART # NON-STERILE	MLI - DIAMETER	LENGTH	DESCRIPTION
731130	741130	11mm	30mm	11mm x 30mm Set Screw
731135	741135	11mm	35mm	11mm x 35mm Set Screw
731140	741140	11mm	40mm	11mm x 40mm Set Screw

13.13 Substantially Equivalent Predicate Devices

TABLE
Predicate Device Identification

NO.	MANUFACTURE'S NAME	DEVICE NAME	510(K) APPROVED
1	DePuy, Inc. Warsaw, IN	DePuy Cannulated Set Screw	Yes
2	Arthrotek, Inc. Ontario, CA	Arthrotek Set Screw	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.

TABLE
Direct Comparison to Already Marketed Products

NO	FEATURE	MLI Set Screw	DEPUY Set Screw
1.	Diameters	9mm and 11mm	9mm
2.	Lengths	20mm, 25mm, 30mm, 35mm and 40mm	20mm, 25mm, 30mm 35mm and 40mm
3.	Materials	Ti-6Al-4V ELI (ASTM - F136)	Ti-6Al-4V ELI (ASTM - F136)
4.	Intended Use	Cruciate Ligament Reconstruction Surgery	Cruciate Ligament Reconstruction Surgery
5.	Cannulated Wire Sizing	0.093" diameter	0.093" diameter
6.	Hex Driver Sizing	3.5mm Hex	4.0mm Hex
7.	Thread Crest	Soft	Soft

NO	FEATURE	MLI Set Screw	DEPUY Set Screw
8.	Taper of inner diameter at proximal end of screw	Yes	Yes
9.	Surface finish	Ti Anodized Coating	High Polish
10.	Self tapping feature	No	No
11.	Flare at distal end of screw	9° Flare	None
12.	Packaging	Sterile and Non-Sterile	Sterile and Non-Sterile

As stated above, MedicineLodge, Inc. believes that the MLI Set Screw is substantially equivalent to the predicate devices indicated in the above table. To demonstrate the substantial equivalence of the MLI Set Screw, it is compared to the DePuy Set Screw.

With regard to the device design, the MLI Set Screw is designed with standard thread geometry. Both the MLI and DePuy sets screws are cannulated to allow use of a 0.093 inch diameter guide wire. Further, both set screws are available in 20mm, 25mm, 30mm, 35mm and 40mm lengths, with the MLI Set Screw available in 9mm and 11mm diameters.

To further elaborate on the design similarities, the proximal use of the MLI - Set Screws tapers at an angle of 45° similar to the DePuy Set Screw.

One of the two minor design differences between the MLI Set Screw and the DePuy Set Screw is the size of the Hex Driver (3.5mm for the MLI Set Screw versus 4.0mm for the DePuy Set Screw). MedicineLodge believes that this design difference does not represent a significant difference in design between the MLI Set Screw and the DePuy Set Screw. The second design difference is the presence of a 9° flare of the internal diameter of the MLI Set Screw at it's distal end which again does not represent a significant difference in functionality of the set screw itself.

To conclude, based on the design concept, indented use, use of standard materials, feature comparisons to selected predicate devices, and device testing, MedicineLodge, Inc. believes that sufficient evidence exists to conclude that the MLI Set Screw is substantially equivalent to existing legally marketed threaded metallic bone fixation fasteners.

13.15 Differences from Predicate Device

MedicineLodge, Inc. would like to claim that the MLI - Set Screw is substantially equivalent to the predicate devices and we find that there are no significant design differences between the subject and predicate device.

Minor modifications such as a 3.5mm hex driver used with the MLI - Set Screw and a 4.0mm hex driver used with the DePuy Cannulated Set Screw do not contribute to the functionality of the implant/device and cannot be considered a significant design change. The 9° flare of the internal diameter of the MLI Set Screw can also be considered a non-functional design difference.

13.16 Performance Testing (Subject and Predicate Devices)

MedicineLodge, Inc. has conducted extensive mechanical testing on the subject and predicate devices to prove substantial equivalence. The following mechanical tests were performed.

a. Fixation strength of the DePuy Cannulated Set Screw in static bone patellar tendon tensile testing in the pig model.
b. Fixation strength of the MedicineLodge, Inc. Set Screw in static bone patellar tendon tensile testing in the pig model.

MedicineLodge, Inc. considers the DePuy Cannulated Set Screw as a suitable predicate device and would like to compare it's Set Screw to the same. The DePuy Set Screw was selected as a predicate due to it's similarity in design. Therefore, for all device testing, a similarly sized 9mm DePuy Set Screw was used for comparison.

The fixation strength testing was conducted on fresh frozen porcine knee specimens. The procedure of surgically placing the set screw and the bone-tendon-bone graft was adapted to mimic the human ACL reconstruction technique. The test results of the DePuy Set Screw and the MLI Set Screws were compared and no statistical significance ($p \leq .005$) could be found between the set screws.

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 - Set Screw is substantially equivalent to existing legally marketed endosteal cruciate fixation devices.