



WRIGHT
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APR 23 1996

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Date: October 6, 1995

510(k) SUMMARY

Trade/Proprietary Name: QuestLock ACL Fixator
Common Name: Staple, fixation, bone device
Classification: Class II
Predicate Devices: The Linvatec Corporation Concept Cannulated Interference Screw and the Mitek Ligament Anchor

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Description/Intended Use

The QuestLock ACL Fixator is intended to provide a means for firmly securing a bone-Patellar Tendon-bone graft during reconstruction of an Anterior Cruciate Ligament (ACL). The fixator is made from Titanium alloy.

Substantial Equivalence

The QuestLock ACL Fixator is substantially equivalent to the The Linvatec Corporation Concept Cannulated Interference Screw and the Mitek Ligament Anchor.

Testing

The QuestLock ACL Fixator demonstrates acceptable pull out strengths.

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