WRIGHT
MEDICAL TECHNOLOGY, INC.

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510(k) Summary

Contact Person:	Cristie Manuel
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Trade/Proprietary Name:	ANCHORLOK™ RL Soft Tissue Anchor System
Classification Name:	Fastener, fixation, nondegradable, soft tissue
Predicate Device:	ANCHORLOK™ RL Soft Tissue Anchor System manufactured for Wright Medical Technology, Inc., and the Statak™ Soft Tissue Attachment Device manufactured by Zimmer.

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 ANCHORLOK™ RL Soft Tissue Anchor System is a single use, sterile kit consisting of a bone anchor with a disposable wire leader and disposable protective sleeve. The anchor is manufactured from titanium alloy.

The ANCHORLOK™ RL Soft Tissue Anchor System is intended for use:

- In the repair of shoulder instability secondary to Bankart lesion, rotator cuff tear, a slap lesion, acromioclavicular separation, biceps tenodesis, deltoid tear/separation, or capsular shift or capsulolabral reconstruction;
- In the repair of elbow instability secondary to biceps tendon detachment, tennis elbow, or ulnar or radial collateral ligament tear/separation;
- In the repair of hand/wrist instability secondary to tear or separation of the scapholunate ligament, ulnar collateral ligament, or radial collateral ligament;
- Female urinary incontinence due to urethral hypermobility;
- In the repair of knee instability secondary to tear or separation of the medial collateral ligament, lateral collateral ligament, patellar tendon, or posterior oblique ligament, or secondary to iliotibial band tenodesis;
- In the repair of foot/ankle instability secondary to tear or separation of the Achilles tendon, lateral stabilization tendons/ligaments, medial stabilization tendons/ligaments, midfoot tendons/ligaments, or metatarsal tendons/ligaments.

Testing Summary

Conclusion: *In vitro* pullout strength testing in the pubis indicates the ANCHORLOK™ RL Anchor can be expected to meet or exceed the pullout strength of the predicate Statak™ anchor.