WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

K971282

JUN 27 1997

510(k) Summary

Contact Person:	Cristie Manuel
Date Prepared:	April 4, 1997
Trade/Proprietary Name:	ANCHORLOK™ and ANCHORLOK™ RL Soft Tissue Anchor System
Classification Name:	Fastener, fixation, nondegradable, soft tissue
Predicate Device:	ANCHORLOK™ and ANCHORLOK™ RL Soft Tissue Anchor System manufactured for Wright Medical Technology, Inc., and the Mitek Anchor manufactured by Mitek Surgical Products, Inc.

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™ and ANCHORLOK™ RL Soft Tissue Anchor System is a single use, sterile device, available in two configurations: the ANCHORLOK™, which is provided sterile, preloaded with suture and a disposable, single use driver, and the ANCHORLOK™ RL, which is provided sterile and is designed for use with reusable, resterilizable driver instrumentation, and suture provided by the surgeon. The anchors for both configurations are made of titanium alloy.

The ANCHORLOK™ and 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;
- Lateral canthoplasty.

Testing Summary

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Christie Manuel
Regulatory Affairs Associate
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

JUN 27 1997

Re: K971282
Anchorlok and Anchorlok RL
Soft Tissue Anchor System
Regulatory Class: II
Product Codes: MBI and HWC
Dated: April 4, 1997
Received: April 7, 1997

Dear Ms. Manuel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

C. **Indications for Use of the Device**

510(k) Number (if known): K971282

Device Name: ANCHORLOK™ and ANCHORLOK™ RL Soft Tissue Anchor System

Indications for Use:

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

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- In the repair of hand/wrist instability secondary to tear or separation of the scapholunate ligament, ulnar collateral ligament, or radial collateral ligament;
- Female uninary 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;
- Lateral canthoplasty

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A. Melvocaler MS, PT for CMW

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971282

Prescription Use X **Or** **Over-the-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)