

*Quality Orthopaedic Instruments and Implants***Appendix F - 510(k) Summary**

MAR 16 1998

**Classification Name:** Bone Anchor  
**Common Name:** Bone Anchor  
**Proprietary Name:** Acumed Suture Anchor  
**Proposed Regulatory Class:** Class II  
**Device Product Code:** JDR, MBI  
**Manufacturing Facility:** Acumed, Inc.  
 10950 SW 5th Street, Suite 170  
 Beaverton, OR 97005 U.S.A.  
**Establishment Registration No.:** 3025141  
**Contact:** Shari Jeffers  
**Labeling/Promotional Materials:** See Appendix D  
**Substantial Equivalence:** This device is identical in indication to the Mitek GII and SuperAnchor (K953877), the Zimmer Statak (K926384), and the Linvatec Revo (K941691). This device is most similar in design to the Zimmer Statak and the Linvatec Revo devices in that all three are based on screw designs and are manufactured from titanium alloys. Literature on Mitek and Linvatec and substantial equivalence information are included in Appendix E.

This summary regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.93.

The Acumed Suture Anchor is a single use implantable device used with non-absorbable, non-coated white or green #2 or #0 braided polyester suture to anchor soft tissue to bone in rotator cuff repairs and soft tissue repairs of the foot and ankle. The suture anchor is manufactured from titanium 6AL 4V ELI per ASTM F 136 and is provided non-sterile. Acumed has identified a set of process parameters for steam sterilization which provide an SAL of  $10^{-6}$  as validated by data on file at Acumed. Information regarding labeling has been provided.

Predicate devices that are substantially equivalent to the Acumed Suture Anchor are the Mitek GII Anchor and SuperAnchor, the Linvatec Revo, and the Zimmer Statak. All the devices mentioned above have the same indications and are manufactured from titanium. The design of the Acumed Suture Anchor is screw based and is similar to the Linvatec Revo and the Zimmer Statak. The Acumed Suture Anchor and the Mitek GII Anchor and SuperAnchor have similar surgical techniques. Based on the similarities between the Acumed Suture Anchor and the predicate devices studied, the safety and effectiveness of the Acumed Suture Anchor is expected to be similar to the predicate devices mentioned above.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 16 1998

Ms. Shari Jeffers  
Regulatory Affairs Manager  
Acumed, Inc.  
10950 SW 5<sup>th</sup> Street, Suite 170  
Beaverton, Oregon 97005

Re: K980103  
Trade Name: Acumed Suture Anchor  
Regulatory Class: II  
Product Code: MBI  
Dated: January 5, 1998  
Received: January 12, 1998

Dear Ms. Jeffers:

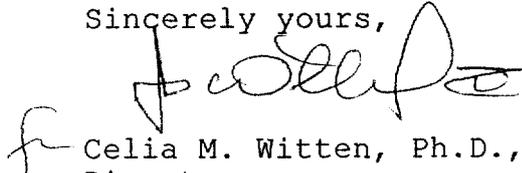
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Pre-market 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 pre-market 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,



f 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

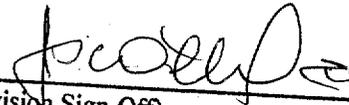
510(k) Number (if known): K980103

Device Name: Acumed Suture Anchor

Indications For Use: This device is intended for anchoring soft tissue to bone in rotator cuff repairs of the shoulder and soft tissue repair of the foot and ankle.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K980103

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)