ACUMED™ K964500

Quality Orthopaedic Instruments and Implants

DEC 9 1996

Enclosure D - 510(k) Summary

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 Tension Band Pin is used in conjunction with orthopedic wire to address malleolar, patella, and oleacranon fracture fixation in tension band wiring procedures. This device is not intended for usage in the spine. This device has a diameter of .0625" and is available in lengths of 35mm, 45mm, and 55mm. The Acumed Tension Band Pin is manufactured from 316L stainless steel and is provided pre-sterile. Sterility is achieved by a minimum dose of 2.5 megarads of gamma radiation. Validation of sterility is maintained on site. Sterility level is 10^{-6}. Information regarding packaging and labeling have been provided.

The Acumed Tension Band Pin is similar to the Acumed Fixation Pin and the Howmedica Kirschner Wire in material and design. Like Howmedica's Kirschner Wire, the Acumed Tension Band Pin is intended to be used in tension band wiring procedures addressing malleolar, patella, and olecranon fractures.

Based on the similarities between the Acumed Tension Band Pin and both the Acumed Fixation Pin and Howmedica Kirschner Wire, the safety and effectiveness is expected to be similar to the Acumed Fixation Pin and Howmedica Kirschner Wire.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 9 1996

Ms. Shari L. Jeffers
Quality Regulatory Coordinator
Acumed Inc.
10950 Southwest 5th Street, Suite 170
Beaverton, Oregon 97005

Re: K964500
Acumed Tension Band Pin
Regulatory Class: II
Product Code: HTY
Dated: November 5, 1996
Received: November 8, 1996

Dear Ms. Jeffers:

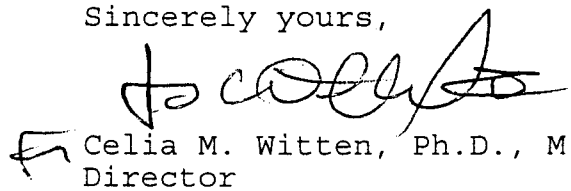
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 "dsmo@fdadr.cdrh.fda.gov".

Sincerely yours,



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): K964500

Device Name: Acumed Tension Band Pin

Indications For Use:

This device is intended to be used in conjunction with orthopedic wire to address malleolar, patella, and olecranon fractures in tension band wiring procedures.

(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 K964500

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)