ACUMED™

Quality Orthopaedic Instruments and Implants

Enclosure D - 510(k) Summary

FEB 19 1997

K965029

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 Stableloc II External Fixation System consists of an external fixation device and a selection of threaded guide pins. The external fixator is not intended for implantation, only as a tool in surgery. It holds in place the pins which provide fracture reduction and alignment. The Stableloc II External Fixation System is used to address Colles' fractures and distal radial osteotomies and is not intended for use in the spine. The Stableloc II External Fixator is manufactured from Ultem, aluminum, stainless steel, and titanium while the guide pins are made from stainless steel per ASTM F 138. The external fixator 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. The guide pins are provided sterile. Sterility is achieved by a minimum of 2.5 megarads gamma radiation. Verification of sterility is performed with the AAMI - Method 1. Sterility level is 10^{-6}. We make no claims as to the pyrogenicity of this product. Information regarding packaging and labeling has been provided.

The Stableloc II External Fixation System is similar to EBI Medical System's Orthofix Dynamic Axial Fixation System in material, intended use, and design. Each system's guide pins are manufactured from stainless steel. Both devices are intended to be used for Colles' fractures and distal radial osteotomies. Both devices are designed to hold two proximal and two distal guide pins and allow the pins to be adjusted. Also, the surgical techniques of both devices are similar. Based on the similarities between the Stableloc II External Fixator and the Orthofix Dynamic Axial Fixator, the safety and effectiveness is expected to be similar to the orthofix Dynamic Axial Fixator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

FEB 19 1997

Re: K965029
Stableloc II External Fixator
Regulatory Class: II
Product Code: JEC and JPS
Dated: December 3, 1996
Received: December 17, 1996

Dear Ms. Jeffers:

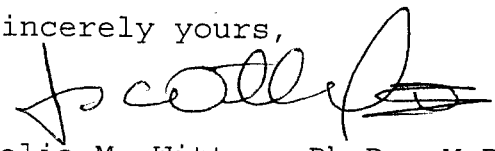
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 "http://www.fda.gov/cdrh/dsmamain.html".

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): K965029

Device Name: Stableloc II External Fixation System

Indications For Use:

This device is used in conjunction with guide pins to address Colles' fractures and distal radial osteotomies.

(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 K965029

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)