



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 5 1995

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

Re: K952330
Small External Fixator
Regulatory Class: II
Product Code: JEC
Dated: September 5, 1995
Received: September 7, 1995

Dear Ms. Jeffers:

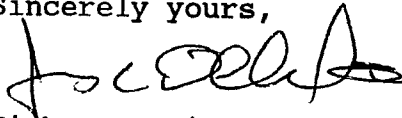
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have 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 practices, 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 (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) 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.

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This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice regarding labeling for your device in accordance with 21 CFR Part 801, promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



fa Kimber C. Richter, M.D.
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

ACUMED inc

Quality Orthopaedic Instruments and Implants

*Sent by
Dave
9/16/95*

September 5, 1995

Mr. Mark Melkerson
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Re: K952330 - Small External Fixator
Dated: May 15, 1995
Received: May 18, 1995

Dear Mr. Melkerson:

The following is in response to your phone request for additional information on September 5, 1995.

First, please find attached rigidity test data comparing the Small External Fixator to Acumed's Stableloc External Fixator, the subject of #K943857.


Second, I would like to definitively identify this device, the subject of #K952330 as the Acumed Small Fixator.

Third, I would like to amend the first sentence of the intended usage section to read: The Acumed Small Fixator is a device used in conjunction with guide pins to achieve fracture reduction and fragment alignment by maintaining distraction forces during fracture healing in the hand.

Fourth, I would like to delete from the device description section the statement: The Mini External Fixator is not intended for implantation, only for use as a tool during surgery. In that same section, I would like to amend the fourth sentence to read: It allows for pin placement and exerts pressure to obtain gross alignment of the digits.

Finally, the additional information submitted in a memorandum dated June 2, 1995 describes Acumed's recommendation for sterilization of the fixation pins by steam autoclaving. If the recommended procedures are followed, the user can expect an SAL of 10^{-6} .

Submitted By:



Shari L. Jeffers
Quality Regulatory Coordinator

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Section I - Intended Use

The Acumed Mini External Fixator is a device used in conjunction with guide pins to achieve optimal fracture reduction and to help correct fragment alignment by maintaining distraction forces during fracture healing in the hand. It is not intended for use in the spine.

Section II - Device Description

The Mini External Fixation System consists of an external fixation device with a selection of threaded guide pins. Instrumentation used with the Mini External Fixator includes a drill, drill guide, pin driver, and a hex key. The Mini External Fixator is not intended for implantation, only for use as a tool during surgery. It promotes accurate pin placement and exerts the appropriate amount of pressure to obtain gross alignment of the digits. The Mini External Fixator is intended for single use only.

Section III - Materials

The Mini External Fixator is manufactured from titanium 6AL/4V ELI per ASTM F 136 and 6061 T6 aluminum. The guide pins are made from 316L stainless steel per ASTM F 138.

Section IV - Sterility and Packaging Information

The Mini External Fixator and the guide pins will be available non-sterile. No packaging information is submitted as the products are provided non-sterile.