



Food and Drug Administration  
1390 Piccard Drive  
Rockville MD 20850

FEB 15 1994

Mr. Gene Conrad  
Product Development Engineer  
Acumed, Inc.  
10950 Southwest 5th, Suite 170  
Beaverton, Oregon 97005

Re: K931244  
Osteo-Clage™ Stainless Steel Bone Plate  
Regulatory Class: II  
Dated: March 11, 1993  
Received: March 11, 1993

Dear Mr. Conrad:

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. This decision is based on your device being found equivalent only to similar devices labeled and intended for long bone fracture fixation. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act).

The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration. Note that labeling or otherwise promoting the device for pedicular screw fixation/attachment would cause the device to be adulterated under 501(f)(1) of the Act.

This device, if intended for use in pedicular screw fixation/attachment, would be found not substantially equivalent and would be a class III device under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing. Accordingly:

1. You may not label or in any way promote this device for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. FDA is currently reviewing widespread off-label use of similar devices that may affect the labeling of this device. You will be notified in writing of any such changes as they occur;
2. All labeling for this device, including the package label, must state that there are labeling limitations.


The package insert must prominently state that the device is intended for long bone fracture fixation only; and

3. Any pedicular screw fixation/attachment to the cervical, thoracic or lumbar vertebral column of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulations under 21 CFR, Part 812. All users of the device for pedicular screw fixation/attachment must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conduct of the investigation.

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. 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 the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device for long bone fracture fixation only. 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 on the labeling for your device system please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-326) 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,



*for* Paul R. Beninger, M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health