DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

MAR - 1 1995

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

Re: K942340
Cannulated Cortical Bone Screw System
K942341
Cannulated Cancellous Bone Screw System
Regulatory Class: II
Product Code: HWC
Dated: November 16, 1994
Received: November 18, 1994

Dear Ms. Jeffers:

This letter immediately will allow you to begin marketing your devices (K942340 and K942341) originally cleared for marketing on December 5, 1994, with the additional indication of humerus fracture repair for the screws up to and including 4.0mm diameter described in your FAX dated February 13, 1995. This determination hereby supersedes and amends our substantial equivalence order of December 5, 1994, and clears for marketing the Cannulated Cortical Bone Screw System and Cannulated Cancellous Bone Screw System only for the indications listed below.

We have reviewed your Section 510(k) notifications of intent to market the devices referenced above and we have determined the devices are substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976 or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). This decision is based on your devices being found equivalent only to similar devices labeled and intended for fractures in the medial malleolus, distal radius, calcaneus, talus, humerus and patella (screws up to and including 4.0mm diameter) and fractures of the tibia and femur (screws larger than 4.0mm diameter). You may, therefore, market your 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. Note that labeling or otherwise

promoting a device for pedicular screw fixation/attachment would cause the device to be adulterated under 501(f)(1) of the Act. This devices, 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. All labeling for these devices, including the package label, must state that there are labeling limitations. The package insert must prominently state that the devices are intended for fractures in the medial malleolus, distal radius, calcaneus, talus, humerus and patella (screws up to and including 4.0mm in diameter) and fractures of the tibia and femur (screws larger than 4.0mm).

2. You may not label or in any way promote this devices for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. If these devices are a screw with outer diameters of 3 mm - 10 mm and overall lengths of 10 mm - 75 mm inclusively, the labeling must include the following statement, **"WARNING:** This devices are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine." Any pedicular screw fixation/attachment to the cervical, thoracic or lumbar vertebral column of these devices 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 devices 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval) they may be subject to such additional controls. Existing major regulations affecting your devices 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. In addition, FDA may publish further announcements concerning your devices 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 immediately will allow you to begin marketing your devices for fracture fixation of the medial malleolus, distal radius, calcaneus, talus, humerus and patella (screws up to and including 4.0mm in diameter) and fracture fixation of the tibia and femur (screws larger than 4.0mm) only, as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and permits your devices 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 devices or its labeling as being approved by FDA. If you desire specific advice regarding labeling for your devices 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,

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