

FEB 4 2000

Appendix F - 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.

Classification Name: Prosthetic, shoulder, humeral (hemi-shoulder), uncemented, metallic
Common Name: Modular shoulder system
Proprietary Name: Acumed Modular Shoulder System
Proposed Regulatory Class: Class II
Device Product Code: HSD
Manufacturing Facility: Acumed, Inc.
 10950 SW 5th Street, Suite 170
 Beaverton, OR 97005 U.S.A.

Establishment Registration No.: 3025141
Contact: Shari Jeffers
Labeling/Promotional Materials: See Appendix D
Substantial Equivalence: This device is similar in size, material, and intended use to the Atlas Modular Shoulder (K961260) and the Select Shoulder System (K962224). This device is most similar in design to the Atlas Modular shoulder in that both devices consist of a head, body, and stem components, have holes for suturing, and have a Morse tapered stem. Literature on the Atlas and Select Shoulder Systems are included in Appendix E.

The Acumed Modular Shoulder System is a semi-constrained modular component designed to address proximal fractures when used with interlocking screws and arthritis of the shoulder joint to be used with or without bone cement. It incorporates a cobalt chrome modular head, a titanium body, and a series of titanium stems. The components may be mixed and matched in order to best duplicate the patient's anatomy. Several strategic holes for suturing are in the body to allow the surgeon to tie down the greater- and lesser-tuberosities, which are frequently displaced during these types of fractures. Interlocking screws identical to those cleared by K942340 Cortical Bone Screws are intended to provide rotational interlocking with the stem. The stems are cannulated and are intended to facilitate placement of the component over a previously inserted guide wire. The component sizing and the geometrical placement of the head and stem are intended to allow the surgeon to duplicate the anatomic posterior offset in the humeral head. Targeting instrumentation is provided to allow accurate placement of the screws through the component.

The Acumed Modular Shoulder System is provided both non-sterile and sterile. The sterile version is packaged in inner and outer PETG blisters with Tyvek lids. Sterility is achieved by a minimum of 2.5 megarads gamma radiation. Verification of sterility is performed using the AAMI - Method 1. Sterility assurance level is 10^{-6} . We make no claims as to the pyrogenicity of this product. Instrumentation is provided nonsterile in a tray. On file at Acumed is data which shows that the instrumentation and implant can be successfully steam sterilized under specific process parameters which will obtain a resulting SAL of 10^{-6} . Information regarding labeling has been provided. Test data provided concludes that the taper selected for the Acumed Modular Shoulder System will provide adequate locking strength for this application.

Predicate devices that are substantially equivalent to the Acumed Modular Shoulder System are the Atlas Modular Shoulder and the Intermedics Select Shoulder. All the devices mentioned above are manufactured from similar materials and have the same intended use. The design of the Acumed Shoulder is most similar to the Atlas Shoulder in that both devices consist of a head, body, and stem components, have holes for suturing, and have a Morse tapered stem. The Acumed Shoulder and the Atlas Shoulder have similar surgical techniques. Based on the similarities between the Acumed Modular Shoulder System and the predicate devices studied, the safety and effectiveness of the Acumed Modular Shoulder System is expected to be similar to the predicate devices mentioned above.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Shari Jeffers
Regulatory Affairs Manager
Acumed, Inc.
10950 SW 5th Street, Suite 170
Beaverton, Oregon 97005

Re: K992525/S1
Trade Name: Acumed Modular Shoulder System
Regulatory Class: II
Product Code: HSD
Dated: November 5, 1999
Received: November 8, 1999

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.

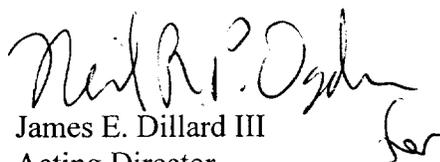
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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 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) 594-4595. 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,

A handwritten signature in black ink, appearing to read "Neil R. Ogden". The signature is written in a cursive style and is positioned above the typed name and title.

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992525

Device Name: Acumed Shoulder Implant

Indications For Use:

Addresses proximal fractures when used with interlocking screws and arthritis of the shoulder joint.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

MPO for JED

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K992525

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use