ACUMED™

Quality Orthopaedic Instruments and Implants

Enclosure D - 510(k) Summary

K960711 MAY -7 1996

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 Acumed Bone Grafting System is a set of various size drills, a Hudson adaptor fitting, a starting punch, a bone plug extractor, and a removal key. A manual drill handle will be added to the system eventually so that the drills may be operated manually. The Hudson adaptor fitting attaches to a standard DC-powered surgical drill. The drill size is selected and attached to the adaptor. The starting punch dimples the bone so a reference point for the drill tip is made. After drilling and harvesting the bone, the drill assembly is removed. The drill piece is detached with the removal key and the bone material is extracted or pushed out by the plug extractor.

The Acumed Bone Graft System is manufactured from 17-4 ph stainless steel. The instruments are provided non-sterile. Data that validates a set of recommended steam sterilization process parameters which obtain a resulting SAL 0f 10^{-6} are maintained on file at Acumed. Information regarding implantation, packaging, and labeling have been provided.

The Acumed Bone Graft System is similar to Wright Medical Technology's Precision Bone Grafting System in form, function, composition, and indications and is expected to perform as well as similar devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 7 1996

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

Re: K960711
Trade Name: Acumed Bone Graft System
Regulatory Class: I
Product Code: KIJ
Dated: February 15, 1996
Received: February 21, 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 at (301) 443-6597.

Sincerely yours,

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

Enclosure

K960711/A

510(k) Number (if known): K960711

Device Name: Acumed Bone Graft System

Indications For Use:

These instruments harvest cancellous bone material from the iliac crest, distal radius, and distal femur and are used in conjunction with another surgical procedure such as bone grafting.

(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 K960711

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)