K97 2108

510(k) Summary

AUG 1 2 1997

Proprietary Name:	Alta® Intramedullary Rod System
Common Name:	IM Rod
Classification Name & Reference:	Intramedullary Fixation Rod 21 CFR 888.3020
Proposed Regulatory Class:	II
Device Product Code:	87HSB

For information contact:

Vivian Kelly
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Date Prepared: June 4, 1997

The IM rods in Alta® IM Rod System consist of a family of curved, fluted rods, cross-locking screws and cap screws for intramedullary nailing of femoral, tibial and humeral shaft fractures. This Alta IM Rod line extension is a modification of the currently marketed Alta IM rods and screws cleared under various 510(k) notifications. These new components will retain the major design features of the previously cleared Alta IM rods and screws and will be made from titanium alloy.

The new femoral IM rods will have two anterior/posterior (A/P) proximal holes and two medial/lateral (M/L) distal holes for dynamic or static locking with cross-locking screws. The cap screws will be available in the standard, low profile and extended designs.

The Alta® IM Rod System includes rods that are intended to provided temporary stabilization of femoral fractures. The new Alta rods are intended for use in stabilizing various types of fractures, osteotomies, malunions, and nonunions of the proximal, middle, and distal portions of the femur. They can be used in procedures such as femoral reconstruction, bone lengthening/shortening, ipsilateral neck/shaft fractures, prophylactic nailing of impending pathologic fractures and knee fusions. The rods are inserted into the intramedullary canal using either an antegrade or a retrograde approach.

The substantial equivalence of these components is based on an equivalence in intended use, materials, design, and operational principles to Howmedica's Alta® IM Rod System and the Alta® CFX Reconstruction Rod, Richard'sTriMax Nail System, ACE Medical's ART™ Femoral Nail System and Biomet's Retrograde Femoral Nail.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Vivian M. Kelly
Manager, Regulatory Affairs
Howmedica Inc.
Pfizer Hospital Products Group
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

AUG 12 1997

Re: K972108
Alta® IM Rod Line Extension
Regulatory Class: II
Product Code: HSB
Dated: June 4, 1997
Received: June 5, 1997

Dear Ms. Kelly:

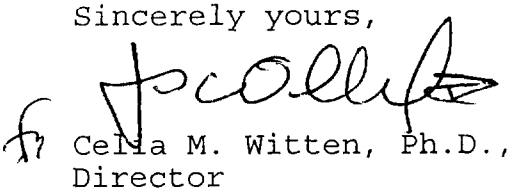
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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.

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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K972108

Device Name: ALTA® IM Rod Line Extension

Indications for Use:

The Alta® IM Rod System includes rods that are intended to provided temporary stabilization of femoral fractures. The new Alta rods are intended for use in stabilizing various types of fractures, osteotomies, malunions, and nonunions of the proximal, middle, and distal portions of the femur. They can be used in procedures such as femoral reconstruction, bone lengthening/shortening, ipsilateral neck/shaft fractures, prophylactic nailing of impending pathologic fractures and knee fusions. The rods are inserted into the intramedullary canal using either an antegrade or a retrograde approach.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972108