

K972479
Sept. 11, 1997

510(k) Summary

Proprietary Name: Alta® Plating System
Common Name: Bone Plate
Classification Name & Reference: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories (21 CFR 888.3030)
Proposed Regulatory Class: II
Device Product Code: 87HRS

For information contact: Vivian Kelly
Manager, Regulatory Affairs
Howmedica Inc.
359 Veterans Boulevard
Rutherford, NJ 07070
Telephone: (201) 507-7830
Fax: (201) 507-6870

The Alta® Modular Trauma System includes various types of plates for internal fixation of fractures. This Alta plate line extension is a modification of the currently marketed Alta Distal Fracture Plates and Channel Plates cleared for under various 510(k) notifications.

These plates are intended to provide temporary stabilization of intra- and extra-articular fractures of the distal femur. Types of fractures include simple and comminuted fractures of the femoral condyles, and selected femoral supracondylar fractures. The plates are used in conjunction with cortical and cancellous bone screws. During healing, the plate provides a buttress for the protection of the fracture fragments. Once healing is complete, the plate will generally be removed.

The substantial equivalence of these components is based on an equivalence in intended use, materials, design, and operational principles to Howmedica's Alta® Distal Fracture Plates and the Alta® Channel Plates.

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SEP 11 1997

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K972479
Alta® Plate Line Extension
Regulatory Class: II
Product Code: HRS
Dated: June 30, 1997
Received: July 1, 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.

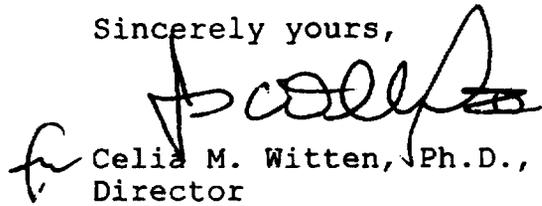
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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) 594-4659. 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

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Indications for Use

510(k) Number (if known):

Device Name: ALTA® Plate Line Extension

Indications for Use:

This Alta® Plating System line extension includes plates that are intended to provide temporary stabilization of intra- and extra-articular fractures of the distal femur. Types of fractures include simple and comminuted fractures of the femoral condyles, and selected femoral supracondylar fractures. The plates are used in conjunction with cortical and cancellous bone screws. During healing, the plate provides a buttress for the protection of the fracture fragments. Once healing is complete, the plate will generally be removed.

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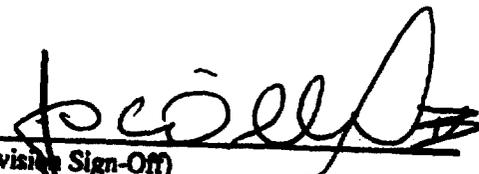
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972479