

OCT 6 1999

K 99 3004

Alta® Fully Threaded Cross-Locking 5.0mm Screw

Special 510(k) Premarket Notification

Special 510(k) Summary - Device Modification  
Summary of Safety and Effectiveness for the  
Alta® Fully Threaded Cross-Locking 5.0mm Screw

Proprietary Name: Alta® Fully Threaded Cross-Locking 5.0mm Screw

Common Name : Intramedullary Fixation Rod

Classification Name and Reference : Intramedullary Fixation Rod,  
21 CFR §888.3020

Proposed Regulatory Class : Class II

Device Product Code : OR (87) HSB

For Information contact: Jennifer A. Daudelin, Regulatory Affairs  
Howmedica Osteonics Corp.  
359 Veterans Boulevard  
Rutherford, NJ 07070-2584  
(201) 507-7283  
Fax: (201) 507-6870

This Special 510(k) submission is intended to address a design modification to the predicate Osteo System Locking Screw. Osteo is a sister division of Stryker for whom Howmedica Osteonics is the sole US Distributor and the US Designated Agent responsible for filing 510(k)s. Throughout this document, the modified Osteo screw will be referred to as The Alta® Fully Threaded Cross-Locking 5.0mm Screw. The Alta® Fully Threaded Cross-Locking 5.0mm Screw is a cross-locking screw with continuous threading along the entire shaft. The design modification involves changing the hex head design to a T25 standard drive feature. The modified device will be a new screw for use with the Alta System. The modified component, the Alta® Fully Threaded Cross-Locking 5.0mm Screw, is substantially equivalent to the predicate device which was cleared for marketing via the 510(k) process. Alta® Fully Threaded 5.0mm Screws are manufactured from Titanium (Ti6Al-4V ELI) Alloy, which conforms to ASTM F-136. The intended use of the Alta® Fully Threaded Cross-Locking 5.0mm Screw is identical to that of the Osteo System Locking Screw.



OCT 6 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Jennifer A. Daudelin  
Regulatory Affairs  
Howmedica Osteonics Corporation  
359 Veterans Boulevard  
Rutherford, New Jersey 07070-2584

Re: K993004  
Trade Name: Alta Fully Threaded Cross-Locking 5.0 mm Screw  
Regulatory Class: II  
Product Code: JDS, HWC  
Dated: August 31, 1999  
Received: September 07, 1999

Dear Ms. Daudelin:

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.

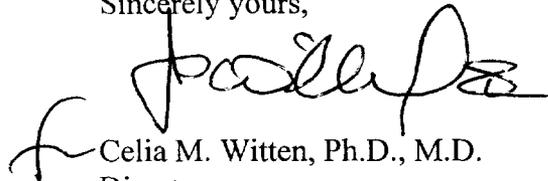
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Ms. Jennifer Daudelin

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, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', is written over the typed name.

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

Alta® Fully Threaded Cross-Locking 5.0mm Screw

Special 510(k) Premarket Notification

Indications for Use

510(k) Number (if known): K993004

Device Name: Alta® Fully Threaded Cross Locking 5.0mm Screw

Indications for Use:

The Alta® Fully Threaded Cross-Locking 5.0mm Screw is indicated for use in fractures requiring static and dynamic locking applications which include the Intramedullary Rods in the Alta® Femoral and Alta® Tibial /Humeral Rod Systems. Specifically, these screws will be used with the Alta® Femoral Locking IM Rod (K850441 & K922266), the Alta® CFX Reconstruction Rod (K926232, K935295, & K960524), the Alta® Tibial/Humeral IM Rod (K884500, K890936, and K954554), and the Alta® Retrograde Rod (K972108).

(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 K993004