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Summary of Safety and Effectiveness

K991889

Encore Orthopedics®, Inc.
9800 Metric Blvd
Austin, TX 78758
512-832-9500

Trade Name: UltiMax Haig II Nail System

Common Name: Compression Hip/Supracondylar Screw

Classification Name: Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component, Metal Composite (Product Code 87LXT)

Device Description: The UltiMax Haig II Nail System is manufactured from titanium (6Al-4V ELI) per ASTM F136 and is light weight. Drawings are provided in Exhibit II.

The barrel and plate (keyed and non-keyed) are one solid piece (non-modular), and is available in 130 °, 135 °, 140 °, 145 ° and 150 ° angles. These are manufactured and tested per ASTM specifications F787. The bone screw hole pattern is offset and 5.0mm cortical screws are used. The most proximal hole accepts a large diameter (7.0mm) cannulated screw. The plates are available in 3 hole, 5 hole, 6 hole, 8 hole, 10 hole, 12 hole and 14 hole lengths.

The UltiMax Haig II Nails are available in 65-125mm (5 mm increments) lengths. The nails are tri-flanged with a series of holes in the proximal end. These holes serve as an enhancement to cement delivery. The Haig II Nail is implanted by direct impaction. Once implanted an adaptor is threaded on the distal end of the nail. A syringe containing a low viscosity bone cement is inserted into the adaptor and cement is delivered into the nail. The cement is pushed through the holes in the proximal end of the nail and dispersed into the femoral head.

Intended Use: The Haig Nail system is indicated for single use to stabilize intracapsular fractures of the neck of the femur; class I, class II, class III, and class IV trochanteric and subtrocanteric fractures with appropriate additional postoperative precautions against weight-bearing and against more than sedentary activity; and arthrodesis of the hip.

Comparable Features to Predicate Device(s): Based on the materials, intended uses, design, testing, and manufacturing, the UltiMax Haig II Nail System is equivalent to the referenced legally marketed comparison devices.

Test Results: The UltiMax Haig II Nail System has been tested by the University of Miami Biomechanics Laboratory at Mount Sinai in Miami Beach, Florida. Based upon ASTM test standards for metallic nail-plate appliances (F787), test results proved the device to be of sound design.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 1999

Ms. Debbie De Los Santos
Regulatory and Clinical Specialist
Encore Orthopedics, Incorporated
9800 Metric Boulevard
Austin, Texas 78758

Re: K991889
Trade Name: UltiMax Haig II Nail System
Regulatory Class: II
Product Code: LXT
Dated: June 2, 1999
Received: June 3, 1999

Dear Ms. De Los Santos:

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 control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

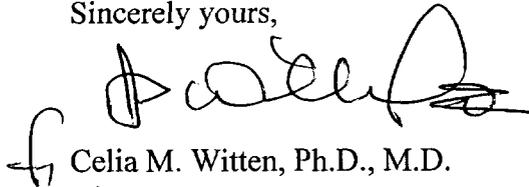
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

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,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

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

510(k) Number (if known): _____

Device Name: UltiMax Haig II Nail System

Indications For Use:

UltiMax Haig II Nail System
Indications For Use

The UltiMax Haig II Nail System is indicated for single use to stabilize intracapsular fractures of the neck of the femur; class I, class II, class III, and class IV trochanteric and subtrochanteric fractures with appropriate additional postoperative precautions against weight-bearing and against more than sedentary activity, and arthrodesis of the hip.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(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 _____

2991889