

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

Trade Name: UltiMax Ankle Fusion Rod System

Common Name: Ankle Fusion Rod

Classification Name: Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3030

Device Description: All components of the UltiMax Ankle Fusion Rod System are manufactured from titanium (6A1-4V ELI) per ASTM F136.

The rod geometry features sharp flutes to obtain initial stability. The rod is bi-diameter to maximize strength in the distal region, tapering down 2mm to accommodate the tibial intramedullary canal. The rod is locked with one or two 5mm transfixing screws in the tibia proximally and are screwed distally in the calcaneus. Rods range in lengths from 150mm to 325mm (25mm increments) and diameters of 11mm and 13mm. Transfixing cortical screws are available in lengths ranging from 60-100mm in 2mm increments.

The rod also features a unique “compression slot” allowing up to 25mm of static or dynamic compression at the ankle joint. This is achieved with compression screws through the distal cannulation being driven against a distal transfixing screw. The compression screws are available in 12mm, 22mm, and 32mm lengths. The rod is fully cannulated for use with a small 2mm guide wire. The small cannulation maintains optimal strength while allowing traditional techniques for rodding.

Intended Use: The UltiMax Ankle Fusion Rod System is indicated for single use for arthrodesis of the ankle joint.

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

Test Results: Testing was performed on the UltiMax Ankle Fusion System. Test results proved the device to be of sound design.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 1999

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

Re: K991790

Trade Name: Ultimax Ankle Fusion Rod System
Regulatory Class: II
Product Code: HSB
Dated: May 24, 1999
Received: May 26, 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.

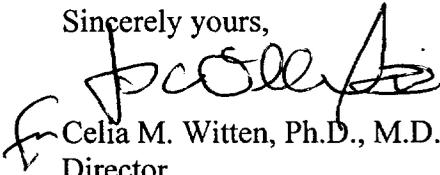
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

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 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". The signature is written in a cursive style with a large initial "C" and "W".

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): K991790

Device Name: UltiMax Ankle Fusion Rod

Indications For Use:

UltiMax Ankle Fusion Rod
Indications For Use

The UltiMax Ankle Fusion Rod System is indicated for single use for arthrodesis of the ankle joint.

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

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 _____

K991790