AUG 1 1 1998

Summary of Safety and Effectiveness

K980854

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

Trade Name: Retrograde Pediatric Nail

Common Name: Femoral Nail

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

Description: The Retrograde Femoral Nail is made of wrought Ti-6Al-4V conforming to ASTM F136. The diameter of the nail tapers from 4.0 mm to 3.6mm with 6 lengths ranging from 19 to 29 cm. Both the proximal and distal ends are bent to provide 3 point fixation. The entire nail is fluted for rotational stability. One end of the nail is threaded to allow for an axial end screw or smooth attachment cap.

Comparable Features to Predicate Device(s): Features comparable to predicate devices include same indications for use and similar geometry.

Test Results: The nail is designed with a bending stiffness of 145lb-in^2 and a torsional stiffness of 112lb-in^2.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 1 1998

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

Re: K980854
Retrograde Pedicatric Nail
Regulatory Class: II
Product Code: HTY
Dated: July 9, 1998
Received: July 13, 1998

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 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,

for Stephen Rhodes

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): K980854

Device Name: Retrograde Pediatric Nail
Indications For Use:

Retrograde Pediatric Nail
Indications For Use

The indications for use of the Retrograde Pediatric Nail include: use in fractures of the femur, tibia and humerus with retrograde applications. Applications would be available in any patients where the growth plate would not be compromised.

(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)_

Steph Rhodes
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980854