zimmer

P.O. Box 708
Warsaw, IN 46581-0708
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SEP 19 1997

K972692

Summary of Safety and Effectiveness
Marchetti-Vicenzi Intramedullary Nail, Humeral

- **Submitted by:**

  Zimmer, Inc.
  P.O. Box 708
  Warsaw, IN 46581-0708

- **Prepared by:**

  Ralph H. Larsen
  Manager
  Global Regulatory Affairs
  Telephone: 219-372-4129
  Telefax: 219-372-4605

- **Date:**

  June 27, 1997

- **Trade Name:**

  Marchetti-Vicenzi Intramedullary Nail, Humeral

- **Common Name:**

  Intramedullary Rod

- **Classification Name:**

  Intramedullary Fixation Rod

- **Predicate Devices:**

  Rush Pins, marketed by Zimmer

K972672

Summary of Safety and Effectiveness
***Marchetti-Vicenzi* Intramedullary Nail, Humeral**
(Continued)

- **Device Description**

The *Marchetti-Vicenzi* Humeral Intramedullary Nail is an intramedullary rod made up of several pins that provide elastic fixation of humeral fractures. The cylindrical, rod-like base of the nail is tapered and is preloaded with either four or five pins. A bolt system holds the tips of the pins together until the nail is properly inserted, at which time the bolt is removed back through the canal and the pins diverge and return to their preconditioned position. The cylindrical base that holds the pins contains a screw hole through which a screw can be inserted for distal locking. Distal locking is required for the humeral nail.

- **Intended Use**

The *Marchetti-Vicenzi* Humeral Intramedullary Nail is a single-use device intended for use in the fixation of fractures of the humerus. Specific indications include all types of fractures and pseudoarthroses occurring between the surgical neck of the humerus and 3 cm proximal to the olecranon fossa.

- **Performance Data**

The *Marchetti-Vicenzi* Humeral Nail exhibited statistically higher bending strength and rigidity in both the 4-pin and 5-pin configurations when compared to Rush Pins.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ralph H. Larsen, RAC
Manager
Global Regulatory Affairs
Zimmer
P.O. Box 708
Warsaw, Indiana 46581-0708

SEP 19 1997

Re: K972692
Marchetti-Vicenzi™ Intramedullary Nail, Humeral
Regulatory Class: II
Product Code: HTY
Dated: July 16, 1997
Received: July 17, 1997

Dear Mr. Larsen:

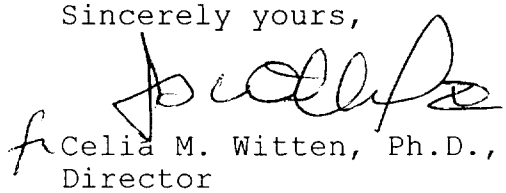
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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: *Marchetti-Vincenzi*™ Intramedullary Nail, Humeral

Indications for Use:

The *Marchetti-Vicenzi* Humeral Intramedullary Nail is indicated for use in the fixation of fractures of the humerus. Specific indications include all types of fractures and pseudoarthroses occurring between the surgical neck of the humerus and 3 centimeters proximal to the olecranon fossa.

(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)

RA06701K.510

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972692