

K964880

OCT 16 1997

Summary of Safety and Effectiveness
for
Vari-Angle Hip Screw System

This safety and effectiveness summary for the Vari-Angle Hip Screw (VHS) System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

1. Submitter :

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Contact Person :

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Telephone: (301) 656-4317

Date Prepared: November 27, 1996

2. Tradename: Vari-Angle Hip Screw (VHS) System

Common Name: Compression Hip Screw System

Classification Name: Single/ multiple component metallic bone fixation appliances and accessories (888.3030)

3. Predicate or legally marketed devices which are substantially equivalent:

- Free-Lock Compression Hip Fixation System (Zimmer)
- AMBI Hip Screw System (Richards)
- Dynamic Hip Screw (DHS) (Synthes)
- Versa-Fx Femoral Fixation System (Zimmer)
- Ace Captured Hip Screw System (Ace Medical)
- Combination NoLok/ Keyed Compression Hip Screw System (DePuy)
- Medoff Sliding Plate (Wright Medical Technology)

4. Description of the device :

The Vari-Angle Hip Screw System is a compression hip fixation system used for the treatment of femoral neck fractures. It consists of adjustable plates, lag screws, compression screws and bone screws.

Materials: The devices are manufactured from 316 LVM stainless steel per ASTM standards.

Function: The system functions to provide immediate stability and temporary fixation during the natural healing process following fractures of the femoral neck.

5. Intended Use:

The Vari-Angle Hip Screw System is indicated for use in the treatment of displaced sub-capital fractures, sub-trochanteric and inter-trochanteric fractures, arthrodesis, moderately displaced femoral capital epiphysis, varus or valgus osteotomies of the hip and medial displacement osteotomies.

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :

There are no significant differences between the Vari-Angle Hip Screw System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 1997

Walter Abendschein, M.D.
5530 Wisconsin Avenue
Suite 705
Chevy Chase, Maryland 20815

Re: K964880
Trade Name: Vari-Angle Hip Screw (VHS) System
Regulatory Class: II
Product Code: KTT
Dated: July 21, 1997
Received: July 21, 1997

Dear Dr. Abendschein:

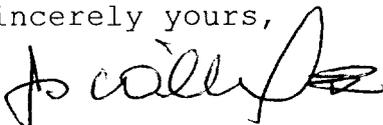
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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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) : K964880

Device Name : Vari-Angle Hip Screw System

Indications For Use :

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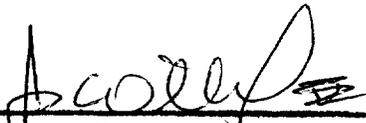
Concurrence of CDRH, Office of Device Evaluation (ODE)

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 K964880