AUG 1 5 2001

K011603

Summary of Safety and Effectiveness
for
VHS™ Pediatric Hip Screw System

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

1. Submitter :
Walter Abendschein, M.D.
5530 Wisconsin Avenue, Suite 705
Chevy Chase, Md. 20815

Date Prepared: May 22, 2001

Contact Person :
Walter Abendschein, M.D.
5530 Wisconsin Avenue, Suite 705
Chevy Chase, Md. 20815
Telephone: (301) 656-4317

2. Tradename: VHS™ Pediatric Hip Screw 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:

- Pediatric Compression Hip Screw System (Smith & Nephew Richards)
- Trauma Internal Fixation System (Smith & Nephew Inc.)
- VHS Vari-Angle Compression Hip Screw System (Biomet)
- Pediatric Osteotomy System (Howmedica)

4. Description of the device :
The VHS™ Pediatric Hip Screw System is a compression fixation system used for the treatment of femoral fractures. It consists of adjustable plates, lag screws, compression screws and bone screws.

Materials: The devices are manufactured from 316 LVM or 22-13-5 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 distal femur.

5. Intended Use:
The VHS™ Pediatric Hip Screw System is used for fracture fixation in the proximal and distal regions of the femur. In particular, indications for use in pediatric patients are as follows :

1. Congenital coxa vara.
2. Congenital dislocation of the hip
3. Subluxation or dislocation secondary to neurologic disorders, such as cerebral palsy, myelomenigocele, poliomyelitis, etc. Usually valgus-anteversion deformities.
4. Coxa plana (Legg-Calve-Perthes disease)

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :
There are no significant differences between the VHS™ Pediatric 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.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 5 2001

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

Re: K011603
Trade Name: VHS™ Pediatric Hip Screw System
Regulation Number: 888.3030
Regulatory Class: II
Product Code: KTT
Dated: May 22, 2001
Received: May 24, 2001

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 (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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) : K011603

Device Name : VHS™ Pediatric Hip Screw System

Indications For Use :

The VHS™ Pediatric Hip Screw System is used for fracture fixation in the proximal and distal regions of the femur. In particular, indications for use in pediatric patients are as follows :

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ___ Yes ___ OR Over-the-counter use ___ No ___

(PER 21 CFR 801.109)

(optional format 1-2-96)

B Mitchell MD for CMW

(Division Sign-Off)

Division of General, Restorative and Neurological Devices

CONFIDENTIAL

510(k) Number K011603