

Summary of Safety and Effectiveness  
for  
**VHS™ Supracondylar Plate System**

This safety and effectiveness summary for the VHS™ Supracondylar Plate 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

**Contact Person :**

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Telephone: (301) 656-4317

Date Prepared: May 26, 1999

**2. Tradename:** VHS™ Supracondylar Plate System

**Common Name:** Supracondylar Plate System

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

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

- Compression Hip Screw Supracondylar Compression Tube & Plate System ( Zimmer )
- AMBI Hip Screw System ( S & N Richards )
- DHS / DCS Dynamic Hip and Condylar Screw System ( Synthes )
- Versa-Fx Femoral Fixation System ( Zimmer )
- Omega Plus Supracondylar Sideplates ( Howmedica )
- Combination NoLok/ Keyed Compression Hip Screw System ( DePuy )
- Medoff Supracondylar Plate System ( Wright Medical Technology )
- BMP Supracondylar Cable Plate System ( Biomet )

**4. Description of the device :**

The VHS™ Supracondylar Plate System is a compression fixation system used for the treatment of distal 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™ Supracondylar Plate System is indicated for use in the treatment of supracondylar fractures and distal femoral fractures.

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

There are no significant differences between the VHS™ Supracondylar Plate 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

AUG - 6 1999

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

Re: K991806  
Trade Name: VHS™ Supracondylar Plate System  
Regulatory Class: II  
Product Code: KTT/KTW  
Dated: May 26, 1999  
Received: May 26, 1999

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 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.

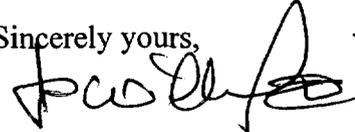
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

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,



f 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): K991806

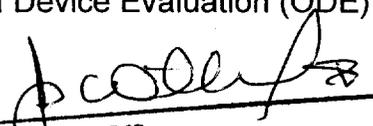
Device Name: VHS Supracondylar Plate System

Indications For Use:

The VHS™ Supracondylar Plate System is indicated for use in the treatment of supracondylar fractures and distal femoral fractures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K991806

Prescription Use Yes  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No

(Optional Format 1-2-96)