

4/29/99

1c990776

**510(K) Summary of Safety and Effectiveness**

**Submitters Name:** *aap* Implants Inc.  
15 Caswell Lane  
Plymouth, MA 02360  
Ph: 508-747-6098 Fax: 508-747-5118

**Contact Name:** Ellen Henke-Knupp, Regulatory Affairs Specialist  
**Name of Device:** *aap* Cannulated Screws and Washers

**Classification Name:** Smooth or threaded metallic bone fixation fastener  
**Common/Usual Name:** Cannulated Bone Screw  
**Proprietary Name:** *aap* Cannulated Screw

**Classification:** Class II Screw, Fixation, Bone # 87 HWC Reg. # 888.3040

**Classification Name:** Washer, Bolt, Nut, Orthopedic  
**Common/Usual Name:** Washers  
**Proprietary Name:** *aap* Washers

**Classification:** Class II Washer, Bolt, Nut, Orthopedic # 87 HTN Reg. # 888.3030

**Performance Standards:** Devices are manufactured according to cGMP's, applicable ASTM requirements, and applicable Harmonized Standards ISO 9001/ EN 46001.

**Material Composition:** The *aap* Cannulated Screws and Washers are manufactured of Titanium Alloy (Ti 6Al 4V E.L.I. = ASTM F-136-96 & ASTM F-1295-97) and 316 L Stainless steel (ASTM F-138-92).

**Intended Use:** *aap*'s Cannulated Screws are intended for use over a guide pin or wire for bone fracture fixation and bone fragment fixation. *aap*'s Washers may be used with the screws in certain applications. Specific indications, which are dependent in part on the diameter of the screw, include: scaphoid fractures and other fractures of the hand; metatarsal fractures and other fractures of the foot; malleolar fractures, ligament fixation of the proximal humerus; wrist, ankle, shoulder and elbow fractures; condylar fractures, fractures of the pelvis and acetabulum; femoral neck and femoral head fractures; femoral supracondylar fractures; and tibial plateau fractures.

**Device Description:** The *aap* Cannulated Screws and Washers are manufactured of Titanium Alloy (Ti 6Al 4V E.L.I.) and 316 L Stainless steel. The *aap* Cannulated Screws are available in various lengths and various thread diameters. The *aap* Washers are available in the appropriate sizes to fit with the screws and are manufactured of Titanium Alloy (Ti 6Al 4V E.L.I.) and 316 L Stainless Steel.

**Predicate Devices for Substantial Equivalency:** *aap* Bone Screws (Stainless Steel & Titanium), OSTEOTECH Cannulated Screws (including Navicular and Cancellous Cannulated Screws)(Stainless Steel 316 L); SYNTHES - Small and Large Cannulated Screw System (Stainless Steel 316L) HOWMEDICA ASNIS II Guided Bone Screws (Stainless Steel 316L), BIODYNAMIC TECHNOLOGIES EZ-Fix™ Cannulated Screw System (Ti 6 Al 4 V E.L.I.), DePuy Cannulated Bone Screw (Stainless Steel 316 LVM), MECRON Cannulated Bone Screws (Stainless Steel 316L) and the ZIMMER Magna-Fx & Mini Magna-Fx Cannulated Screw Fixation System (Stainless Steel).

**Comparison of Technological Characteristics:** The *aap* Cannulated Screws and Washers are substantially equivalent to the predicate devices with respect to physical/technical and material characteristics.

**Sterilization Information:** These devices are distributed non-sterile, recommendations for sterilization are contained in the package insert. Note: These devices are sterilized by the end users utilizing the approved/ outlined guidelines found in the AAMI Guideline "Good Hospital Practice: Steam Sterilization and Sterility Assurance" and in ANSI/AAMI/ISO 11737 guidelines to achieve the acceptable Sterility Assurance Level (SAL) of 10<sup>-6</sup>.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 29 1999

Ms. Ellen J. Henke-Knupp  
Regulatory Affairs Specialist  
aap Implants, Inc.  
Boat Yard Square  
15 Caswell Lane  
Plymouth, Massachusetts 02332

Re: K990776  
Trade Name: aap Cannulated Screws  
Regulatory Class: II  
Product Code: HWC  
Dated: March 4, 1999  
Received: March 9, 1999

Dear Ms. Henke-Knupp:

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.

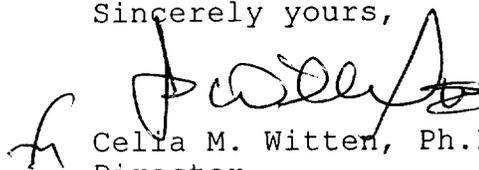
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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,

A handwritten signature in black ink, appearing to read "C. Witten", is written over the typed name. To the left of the signature is a small handwritten mark that looks like the letter "h".

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): K990776

Device Name: aap Cannulated Screws and Washers

Indications For Use:

aap's Cannulated Screws are intended for use over a guide pin or wire for bone fracture fixation and bone fragment fixation. aap's washers may be used with the screws in certain applications.

Specific Indications any include:

- scaphoid fractures and other fractures of the hand
- metatarsal fractures and other fractures of the foot
- malleolar fractures
- ligament fixation of the proximal humerus
- wrist, ankle, shoulder and elbow fractures
- condylar fractures
- fractures of the pelvis and acetabulum
- femoral neck and femoral head fractures
- femoral supracondylar fractures
- tibial plateau 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 K990776

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_