DEC 2 7 2004

Summary of Safety and Effectiveness for the Herbert Ulnar Head Prosthesis System

submitted by
OrthoSurgical Implants, Inc.
12244 SW 130 St
Miami, FL 33186
Phone: (305) 969-4545

Contact Person:	Ricardo Schoening
Device Trade Name:	Herbert Ulnar Head Prosthesis System
Common Name:	Ulnar Head Prosthesis
Classification Name:	Wrist joint ulnar (hemi-wrist) polymer prosthesis per 21 CFR § 888.3810

Identification of a Legally Marketed Predicate Device

The OrthoSurgical Implants, Inc. Herbert Ulnar Head Prosthesis System is substantially equivalent to uHead Ulnar Implant System that is legally marketed and distributed by Avanta Orthopaedics, Inc. pursuant to premarket notification K010786.

Device Description

The Herbert Ulnar Head Prosthesis System consists of an intramedullary ulnar stem made of titanium, a Co/Cr or Zirconia ulnar head, and a surgical instrumentation set.

Intended Use

The Herbert Ulnar Head Prosthesis System is indicated for ulnar head and stem replacement necessitated by: 1) Failed operative procedures such as Darrach, Bowers, or Sauve-Kapandji, 2) Primary osteoarthritis, 3) Post –traumatic osteoarthritis as a result of radial fractures, TFCC tears, ulnar impingement, 4) Rheumatoid arthritis, and 5) Tumors.

Summary of Technological Characteristics

An 8-point comparison of technological characteristics of the OrthoSurgical Implants, Inc. Herbert Ulnar Head Prosthesis System and the predicate devices was performed. The devices were found to be substantially equivalent.

Summary of Performance Data

The OrthoSurgical Implants, Inc. Herbert Ulnar Head Prosthesis System complies with the requirements of listed FDA Recognized Consensus Standards.

- ISO 5832-2:1999, Implants for Surgery — Metallic Materials — Part 2: Unalloyed Titanium
- ISO 5832-3:1996, Implants for Surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy
- ISO 5832-12:1996, Implants for Surgery — Metallic materials — Part 12: Wrought cobalt-chromium-molybdenum alloy
- ISO 7153-1:1991/Amd. 1:1999, Surgical instruments — Metallic materials — Part 1: Stainless steel
- ASTM F899 – 95, Standard Specification for Stainless Steel Billet, Bar and Wire for Surgical Instruments
- ASTM F138 – 97, Standard Specification for Wrought 18 Chromium–14 Nickel–2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)
- AAMI/ANSI/ ISO 11134:1993, Sterilization of health care products - Requirements for validation and routine control-industrial moist heat sterilization.
- AAMI/ANSI ST46:2002, Steam Sterilization and Sterility Assurance in Health Care Facilities

The OrthoSurgical Implants, Inc. Herbert Ulnar Head Prosthesis System is substantially equivalent to the uHead Ulnar Implant System that is legally marketed and distributed by Avanta Orthopaedics, Inc. This has been demonstrated through a 8-point technological comparison of features.

The blood and tissue contact materials used to fabricate the Herbert Ulnar Head Prosthesis System have a long history of safe usage in medical devices. Because the OrthoSurgical Implants, Inc. Herbert Ulnar Head Prosthesis System meets the requirements of the stated standards and embody technological characteristics essentially identical to the predicate device, we believe the device is safe and effective and performs as well as or better than the predicate device. The Herbert Ulnar Head Prosthesis System will be manufactured per specifications using good manufacturing practices that ensure the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 27 2004

Stuckenbrock Medizintechnik GmbH
C/o Mr. Al Weisenborn
OrthoSurgical Implants, Inc.
12244 SW 130 Street
Miami, Florida 33186

Re: K042902
Trade/Device Name: Herbert Ulnar Head Prosthesis System
Regulation Number: 21 CFR 888.3810
Regulation Name: Wrist joint ulnar (hemi-wrist) polymer prosthesis
Regulatory Class: II
Product Code: KXE
Dated: September 27, 2004
Received: October 20, 2004

Dear Mr. Weisenborn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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.

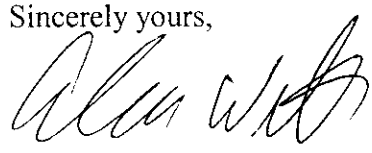
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/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

Indications for Use

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510(k) Number (if known): K042902

Device Name: Herbert Ulnar Head Prosthesis System

Indications for Use:

The Herbert Ulnar Head Prosthesis System is indicated for ulnar head and stem replacement necessitated by: 1) Failed operative procedures such as Darrach, Bowers, or Sauve-Kapandji, 2) Primary osteoarthritis, 3) Post -traumatic osteoarthritis as a result of radial fractures, TFCC tears, ulnar impingement, 4) Rheumatoid arthritis, and 5) Tumors.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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, Restorativ
and Neurological Devices

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