

K 964878

510(k) SUMMARY - ESOP® S/C FEMORAL STEM

MAR - 5 1998

**Submitter Name:** Fournitures Hospitalieres  
Office Medico Chirurgical International

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**Date Prepared:** December 5, 1996

**Device Trade Name:** ESOP® S/C Femoral Stem

**Device Common Name:** Hip Stem

**Classification Name:** Prosthesis, Hip, Femoral Component (Metal Stem -  
Ceramic Head)

**Predicate Devices:** Primaloc® Cementless Hip System (K953977),  
Ortho Development Corporation;  
  
Intrinsic® Cementless Total Hip System (K923911),  
Ortho Max, Inc.

**Device Description:** The ESOP® S/C Femoral Stem consists of a ceramic head,  
left and right configuration metaphysary parts in various  
size diameters, and diaphysary parts in various sizes. The  
ESOP® S/C instrumentation system is utilized for proper  
implantation of the device.

**Intended Use:** The ESOP® S/C Femoral Stem is intended for use in  
degenerative and inflammatory arthritis of the hip joint,  
trauma, non-acute femoral neck fracture, revision of  
previously failed hip arthroplasties, and idiopathic  
avascular (osteo) necrosis where radiographic evidence  
shows there exists sufficient sound bone to seat the  
prosthesis. This device is intended for cementless  
application.

Continued . . .

**510(k) Summary (continued)**

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**Device Technological Characteristics and Comparison to Predicate Devices:**

The ESOP® S/C Femoral stem design includes: 2 ceramic heads with short, medium, or long necks; 10 left and right configuration metaphysary parts in various size diameters with a 10° relief to the lateral side of the metaphys for ease of insertion into the femoral canal; and 7 diaphysary parts in various sizes which are to be screwed into the extremity of the metaphyseal part. Identified predicate devices have the same intended use and may incorporate some of or all of the above described design features either alone or in combination.

**Performance Data:**

Testing conducted to characterize the materials, the hydroxylapatite coating, and the performance characteristics of the device under defined laboratory conditions was provided to support a finding of substantial equivalence.

**Conclusion:**

The ESOP® S/C Femoral Stem is substantially equivalent to predicate device in terms of intended use, safety, and effectiveness.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Ben Van der Kooij  
Director, Europe/USA  
Pro-Active International  
Regulatory Agent for Fournitures Hospitalieres  
c/o Advanced Bioresearch Associates  
1700 Rockville Pike, Suite 450  
Rockville, Maryland 20852

MAR - 5 1998

Re: K964878  
ESOP® S/C Femoral Stem  
Regulatory Class: II  
Product Codes: MEH and LZ0  
Dated: December 5, 1997  
Received: December 5, 1997

Dear Mr. Van der Kooij:

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). This decision is based on consideration of the specific design of stem and coating composition detailed in this application. You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitations:

1. The package insert must reflect that the ESOP® Femoral Ceramic Heads are to be used only with the titanium alloy cone of the ESOP® S/C Femoral Stem.
2. You may not label or in any way promote these devices for "biological attachment, enhanced clinical or radiographic performance, enhanced fixation and/or long-term stable fixation." The data presented support equivalence with no additional claims over a conventional press-fit hip prosthesis (i.e., mechanical interlock, only).

Additional limitations for more specific claims of safety and effectiveness may be forthcoming. Should additional limitations be applied you will be contacted in writing to inform you of the additional labeling limitations.

Page 2 - Mr. Ben Van der Kooij

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.

You may market your device under the above limitations as class II devices. These devices would be considered not substantially equivalent to a legally marketed predicate device if labeled with other intended uses and/or claims of safety or effectiveness. Any other intended uses or claims may cause the device to be classified into Class III under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing.

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. 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.

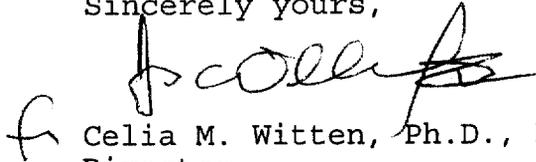
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the 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

Page 3 - Mr. Ben Van der Kooij

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". The signature is written in a cursive style with a large initial "C" and a long horizontal stroke.

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

