JUN - 5 1997 K970846

SUMMARY OF SAFETY AND EFFECTIVENESS

MANUFACTURER IDENTIFICATION:

Landanger-Landos
Z.I. La Vendue BP 88
52003 Chaumont FRANCE

SPONSOR IDENTIFICATION:

Cheryl Hastings
Manager, Clinical Affairs
DePuy Orthopaedics, Inc.
P.O. Box 988
Warsaw, IN 46581-0988

ESTABLISHMENT REGISTRATION NUMBER:

1818910

PROPRIETARY NAME:

22.2/+4mm Femoral Heads

PRODUCT CLASSIFICATION CODE:

87 LZO

PROPOSED REGULATORY CLASS:

Class II

PREDICATE DEVICES:

Morphometric Total Hip Prosthesis (K935185)

DESCRIPTION:

The **22.2/+4 Femoral Head** is designed to fit on a 9/11 taper. It is 22.2mm in diameter and has a neck length of +4. It is available in zirconia or cobalt chrome alloy.

INDICATIONS AND INTENDED USE:

The intended use for the 22.2/+4 Femoral Head is to complete the assembly of a Ti-6Al-4V semi-constrained femoral hip stem with a 9/11 Morse-like taper, identical to the taper of the Morphometric Hip, manufactured by Medinov-AMP. The indications for use are arthritis, arthrosis or any joint disease at the hip level, osteosynthesis, failed previous surgery or joint reconstruction.

SUMMARY OF TESTING DATA:

The burst load average for both the zironia and cobalt chrome heads is substantially equivalent to that of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 1997

Ms. Cheryl Hastings
Manager, Clinical Affairs
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K970846
22.2/+4 Femoral Head (Co-Cr Alloy or Zirconia)
for use with Morphometric Hip Stem K935185
Regulatory Class: II
Product Codes: LZO and JDI
Dated: March 5, 1997
Received: March 7, 1997

Dear Ms. Hastings:

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 and the following limitation that the package insert must reflect that the Zirconia Ceramic Femoral Heads are to be used only with Ti-6Al-4V Morphometric hip stems with the 5°43'30" Morse taper trunnions.

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 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

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,

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) K970846

Device Name 22.2/+4 Femoral Head

Indications for Use:

The intended use for the 22.2/+4 Femoral Head is to complete the assembly of a Ti-6Al-4V semi-constrained femoral hip stem with a 9/11 Morse-like taper, identical to the taper of the Morphometric Hip, manufactured by Medinov-AMP. The indications for use are arthritis, arthrosis or any joint disease at the hip level, osteosynthesis, failed previous surgery or joint reconstruction.

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K970846

Prescription Use X OR Over-The Counter Use_____