

SUMMARY OF SAFETY AND EFFECTIVENESS

JUL - 8 1997

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:

KAR Revision Hip Prosthesis

PRODUCT CLASSIFICATION CODE:

87 MEH

PROPOSED REGULATORY CLASS:

Class II

PREDICATE DEVICES:

Osteonics Restoration Monolithic Hip
Implex F-220 Press-Fit Femoral System
Landanger-Landos Corail Hip

DESCRIPTION:

The KAR Revision Hip is a non-cemented, long femoral stem made from Ti-6Al-4V, completely coated with hydroxyapatite. It has a straight stem with a quadrangular cross-section and blunt corners. The metaphyseal widening presents a bi-dimensional flare and horizontal and vertical grooves for metaphyseal support. The step-like structure of the grooves in the metaphyseal section provides stability. The distal section has symmetrical slopes. The length of the diaphyseal section provides a distal anchor while the distal cross-slotted tip allows for elasticity in the stem and adaptability to the femoral curve. The stem has a 12/14 Morse-like taper.

INDICATIONS AND INTENDED USE:

The KAR Hip Prosthesis is recommended for revision cases. It is intended for use as a press-fit femoral hip prosthesis where there is evidence that there is sufficient healthy cortical bone to seat the femoral component. This prosthesis is indicated for use in the following conditions: a severely painful and/or severely disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis; avascular necrosis of the femoral head; acute traumatic fracture of the femoral head or neck; or failed previous surgery including joint reconstruction, internal fixation, arthrodeses, hemiarthroplasty, surface replacement arthroplasty, or other total hip replacement.

SUMMARY OF CLINICAL DATA:

Clinical studies indicate that the KAR femoral stem, a revision version of the Corail femoral stem, has a comparable success rate to the Corail. Compared to the Osteonics Restoration Monolithic Hip Stem, the KAR had fewer post-operative complications and better Postel Merle D-Aubigne scores.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K961732
Trade Name: KAR Hip Prosthesis
Regulatory Class: II
Product Codes: LZO and MEH
Dated: June 5, 1997
Received: June 9, 1997

JUL - 8 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 limitations:

1. The package insert must reflect that the the KAR Hip Prosthesis, made of Ti 6 Al-4V, with 5⁹42'30" Morse taper trunnion only be used with the cobalt chrome femoral heads described within this submission, or Alumina femoral heads cleared under K905298, K933567, K932935, or K933108; and
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.

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.

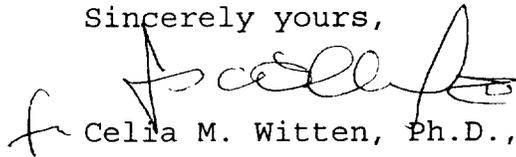
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the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

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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 "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "W".

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

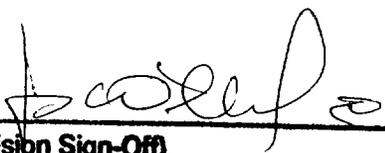
510(k) Number (if known) K961732

Device Name KAR Revision Hip Prosthesis

Indications for Use:

This prosthesis is intended for use as a press-fit femoral hip prosthesis where there is evidence that there is sufficient healthy cortical bone to seat the femoral component. This prosthesis is indicated for use in the following conditions: a severely painful and/or severely disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis; avascular necrosis of the femoral head; acute traumatic fracture of the femoral head or neck; or failed previous surgery including joint reconstruction, internal fixation, arthrodeses, hemiarthroplasty, surface replacement arthroplasty, or other total hip replacement.

Concurrence of CDRH, Office of Device Evaluation



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K961732

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____