



JUL 6 1994

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

Mr. David A. Kotkovetz
.Coordinator, Regulatory Affairs
DePuy Inc.
PO Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K934457
Stability Hip Stem with Porocoat®
Regulatory Class: II
Product Code: LZ0
Dated: September 10, 1993
Received: September 13, 1993

Dear Mr. Kotkovetz:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. This decision is based on consideration of the specific design of stem, data provided for the reclassified Biolox Ball manufactured by Cersiv (formerly Feldmuhle Aktiengesellschaft), and data provided for the Biolox 2 Ball contained in the identified premarket notification. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitation:

The stem is labeled for use only with the Biolox 2 Balls having the following Cerasiv Model numbers:

- a. 38.39.7105.015.0.9
- b. 38.39.7105.025.0.2
- c. 38.39.7105.195.0.2
- d. 38.39.7105.205.0.4
- e. 38.39.7105.215.0.8

The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

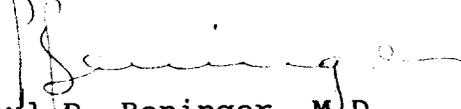
You may market your device under the above limitations as class II devices. These devices would be considered not substantially equivalent to a legally marketed predicate

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. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. 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, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-300) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



Paul R. Beninger, M.D.
Director

Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health



X. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

**SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary**

NAME OF FIRM: DePuy Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

510(K) FIRM CONTACT: David A. Kotkovetz
Coordinator, Regulatory Affairs

TRADE NAME: Stability Hip Stem with Porocoat®

COMMON NAME: Femoral Prosthesis

CLASSIFICATION: 888.3360 Prosthesis, Hip, Femoral
Component Uncemented, Metal

DEVICE PRODUCT CODE: Product code: 87KWL

**SUBSTANTIALLY
EQUIVALENT DEVICES:** - Stability Hip Stem with Porocoat -
DePuy

- AML Porocoat Femoral Stem - DePuy

**DEVICE DESCRIPTION
AND INTENDED USE:** The Stability Hip Stem with Porocoat
porous coating is a femoral hip prosthesis.
Each stem has a self-locking taper which
allows for the use of interchangeable
modular femoral heads.

The proximal body is porous coated
(Porocoat) with commercially pure titanium
beads and includes numerous
circumferential ridges.

A coronal slot in the distal stem allows the
distal portion of the implant to flex slightly
with the femur. The distal stem also
includes flutes, intended to provide
rotational stability.

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The Stability Hip Prosthesis is indicated for uncemented use as the femoral component in total hip arthroplasty for replacing the hip joint of patients whose hip joint has been damaged by degenerative joint disease, fracture, or the failure of a previous arthroplasty. The articular surface of the prosthesis is provided by the attachment of a modular femoral head of cobalt-chromium-molybdenum alloy (Orthochrome) or aluminum oxide ceramic (Bilox) for use in total hip replacement with a porous coated metal-backed acetabular component with a bearing surface made of ultra high molecular weight polyethylene. Fixation of the Stability Hip to the skeleton is intended to be by uncemented, biological fixation by tissue ingrowth into the porous coating.

**BASIS OF
SUBSTANTIAL
EQUIVALENCE:**

The DePuy Stability Hip Stem with Porocoat for uncemented application is substantially equivalent (i.e., identical) to the Stability Hip Stem with Porocoat for cemented application (K915787) in design and material. Both include a porous coating on the proximal body. The material of the DePuy Stability Hip Stem with Porocoat remains unchanged. The proximal region of the Stability Hip Stem with Porocoat includes numerous circumferential ridges which remain unchanged. The distal stem of the Stability Hip Stem with Porocoat is fluted and slotted and remains unchanged. The intended use for the Stability Hip Stem with Porocoat in the K915787 submission is for cemented application; whereas, the intended use of the Stability Hip Stem with Porocoat in this submission is for uncemented (i.e., press-fit applications).

The DePuy Stability Hip Stem with Porocoat for uncemented application is substantially equivalent to the AML Porocoat Femoral Stem in intended use. Both stems are intended to be used in

uncemented (i.e, press-fit) applications. Both stems are porous coated (Porocoat) to enhance the strength of the bone/prosthesis interface. The porous coated surface is proximally located on the Stability Hip Stem and includes numerous circumferential ridges; whereas, the porous coated surface on the AML Hip covers the entire stem except the distal 5cm and does not have proximally located ridges. The Stability Hip distal stem is fluted and slotted; whereas, the AML distal stem is not fluted or slotted. The material of the Stability Hip Stem is a titanium alloy; whereas, the AML Hip Stem is a cobalt-chrome alloy. The articular surface of both stems is provided by the attachment of a modular femoral head. The Stability Hip Stem does not have a calcar collar; whereas, the AML Hip Stem has a calcar collar.

Note: The AML Porocoat Femoral Stem approved for uncemented application is now a Regulatory Class II device pursuant to the reclassification order issued by the FDA and effective February 21, 1992.

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