EXHIBIT

F

K915787

APR 29 1993

SAFE MEDICAL DEVICES ACT OF 1990

SAFETY & EFFECTIVENESS SUMMARY:

1. The DePuy Stability Hip Femoral component is a one-piece stem. The material is a titanium alloy (Ti-6Al-4V) and is the same as the S-Rom Total Hip stem. The design of the proximal body and stem of the DePuy Stability Hip Femoral component is similar to that of the S-Rom Total Hip stem. The intended use of the DePuy Stability Hip Femoral component is the same as the two (2) above-mentioned substantially equivalent devices in the use of bone cement for fixation.

2. The DePuy complaint file was reviewed for the AML femoral stems from 1986 to current date (i.e. five (5) years).

3. A literature and MDR computer search was performed on femoral stems.

4. The search of DePuy's complaint files and a literature and MDR search is considered to be a reasonable search for adverse safety and effectiveness information. The results of the search can be referenced in Item #5 (below).

5. A summary of "possible" causes of safety/effectiveness problems are as follows: inadequate bone cement technique, femoral neck fractures, and loosening of bone/cement/prosthesis interface.

6. It is concluded that the safety and effectiveness of the DePuy Stability Hip Femoral component will not be different from devices marketed currently.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

APR 29 1993

Mr. David A. Kotkovetz
Regulatory Affairs Coordinator
DePuy Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46580

Re: K915787
Stability Hip Prosthesis with Porocoat
Regulatory Class: II
Dated: October 9, 1992
Received: October 13, 1992

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 to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976. This decision is based on porous-coated devices being equivalent only to similar devices labeled and intended to be fixed within bone with acrylic "bone cement" and alumina femoral balls having data provided for the reclassified Biolox Ball manufactured by Feldmuhle Aktiengesellschaft. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. This device may not be labeled or promoted for non-cemented use.

2. The stems are labeled for use with the CoCr femoral balls as stated in the 510(k) and Biolox Balls having the following Feldmuhle Model numbers:

   38.39.7105.015.0.9
   38.39.7105.025.0.2
   38.39.7105.195.0.2
   38.39.7105.205.0.4
   38.39.7105.215.0.8

3. All labeling for this device, including package label and labeling included within the package, must prominently state that the device is intended for cemented use only.

investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device for non-cemented fixation must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.

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.

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. 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 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 Division of Compliance Operations, Device Labeling Compliance Branch (HFZ-326) at (301) 427-1342. 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.
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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