



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 11 1991

Food and Drug Administration  
1390 Piccard Drive  
Rockville MD 20850

Mr. J. D. Webb  
Director  
Regulatory and Clinical Affairs  
Intermedics Orthopedics, Inc.  
1300 East Anderson Lane  
Building C  
Austin, Texas 78752

Re: K913060  
Natural Porous Hip System  
Regulatory Class: II  
Dated: September 9, 1991  
Received: September 10, 1991

Dear Mr. Webb:

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 when labeled for cemented use only. This decision is based on data provided for the reclassified BioloX® ball manufactured by Feldmuhle Aktiengesellschaft and the porous coated Ti-6Al-4V stem. 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. The stem may only be labeled for use with the following BioloX® balls:

39.7150.215	(32mm long)
39.7150.205	(32mm medium)
39.7150.195	(32mm short)
39.7150.025	(28mm medium)
39.7150.015	(28mm short)
2. This device may not be labeled or promoted for non-cemented use.
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.

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The general controls provisions of the Act include requirements for annual 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, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. 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,

*for* 

Carl A. Larson, Ph.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health