DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Carol J. Freasier
Regulatory Affairs/Quality Assurance Specialist
Ortho Development Corporation
106 West Business Park Drive
Draper, Utah 84020

JUL - 9 1997

Re: K971435
Headloc™ Alumina and Zirconia Ceramic Heads
Regulatory Class: II
Product Code: LZO
Dated: April 16, 1997
Received: April 18, 1997

Dear Ms. Freasier:

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 Headloc™ Alumina Ceramic Femoral Heads are to be used only with CoCrMo alloy hip stems with the CeramTec 2°52'30" Morse taper trunnions, and Headloc™ Zirconia Ceramic Femoral Heads are to be used only with CoCrMo or Ti6Al4V alloy hip stems with the CeramTec 2°52'30" 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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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

Ortho Development Corporation
Premarket Notification for Headloc™ Ceramic Femoral Heads
510(k) Number (if known): K971426

Device Name: Headloc™Ceramic Femoral Head

Indications for Use

The Headloc™ Ceramic Femoral Head for the Primaloc™ Cementless Hip System is intended for single-use cementless implantation during primary/revision surgery. The Ceramic Head allows for primary articulation between the acetabular cup and femoral stem to restore patient mobility. Indications for use are:

- Osteoarthritis, rheumatoid arthritis, or other osteoarthroses;
- Certain femoral neck fractures or dislocations;
- Post-traumatic arthritis;
- Idiopathic avascular necrosis of the femoral head;
- Benign or malignant bone tumors where sufficient bone stock exists to seat the prosthesis;
- Previous failed surgery;
- Total hip replacement where the surgeon indicates a ceramic head

The Headloc™ Ceramic Head may be used with the Primaloc™ Cemetless Hip System which is cleared for use under Premarket Notification K953977.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971425

Prescription Use X OR Over-The-Counter Use_____

(Optional Format 1-2-96)