

JUN 25 1998

510K SUMMARY OF SAFETY AND EFFECTIVENESS

The Signal Medical Corporation 28mm Ceramic Femoral Heads are manufactured from zirconium oxide. The design is made available in three (3) sizes identical to the cobalt chrome femoral heads in the Signal Medical Corporation 510K (K971681) (-3.5, 0, +3.5). These ceramic femoral heads should only be used on the Signal Medical Corporation (SMC) femoral component of the hip, and should never be resterilized.

Indications for use

1. Osteoarthritis
2. Rheumatoid Arthritis
3. Traumatic Arthritis
4. Where the use of a more conservative procedure has failed or is unacceptable.



JUN 25 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Louis A. Serafin, Jr., M.D.
Signal Medical Corporation
3315 Berry Drive
Lakeport, Michigan 48059

Re: K981302
SMC Ceramic Femoral Head - 28 mm
Regulatory Class: II
Product Code: LZ0
Dated: April 6, 1997
Received: April 9, 1997

Dear Dr. Serafin:

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 Signal Medical Corporation's 28 mm Zirconia Ceramic Femoral Head is only to be used with Signal Medical Corporation's cobalt-chrome hip stems with the 5.708 degree trunnions. This information must be identified in the package insert.

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.

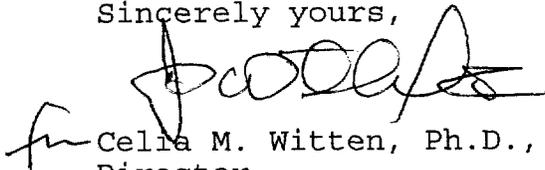
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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

510(k) Number (if known): _____

Device Name: SMC 28MM CERAMIC FEMORAL HEAD

Indications For Use:

1. OSTEOARTHRITIS
2. RHEUMATOID ARTHRITIS
3. TRAUMATIC ARTHRITIS
4. WHERE THE USE OF A MORE CONSERVATIVE PROCEDURE HAS FAILED OR IS UNACCEPTABLE.

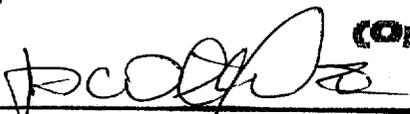
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
Counter Use _____
(Per 21 CFR 801.109)

OR Over-The-

(Optional Format)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981302