K971681 DEC -4 1997

510K SUMMARY OF SAFETY AND EFFECTIVENESS

The Signal Medical Corporation Femoral Component of the Hip is manufactured with cobalt chromium alloy (ASTM F-75). The design is made available in four (4) sizes ranging from 10.5mm to 15mm. The stem portion of the femoral component is essentially identical to the DePuy AML Femoral Component (K852198) and the BioPro Horizon Femoral Component (K962769). The collar will be available in two different angular settings of 20 degrees to the horizontal and 35 degrees to the horizontal. The device will be offered with and without a sintered beaded surface, as depicted on the engineering drawings. The taper on the trunnion is a standard 5.708 degree angle as found on the Whiteside Biomechanics (K961625) and the StelKast Proform Cemented Femoral Component (K951083). The device has a circumfrential collar to load the bone on the cortical arc and distribute the compressive load of the implant as proximally as possible. The stems distal to the collar are essentially identical in geometry and size as the DePuy AML (K852198) and the BioPro Horizon (K962769). The non-sintered beaded surface device will have a 5mm hole in the distal tip of the implant to accommodate a cement centralizer from the StelKast Corporation (K951083).
If further information is required please contact Dr. Louis Serafin, Signal Medical Corporation, 3315 Berry Drive, Lakeport, MI 48059, phone - 810-385-8302.
This device is designed for cemented use only in the non-porous coated version. With the porous sintered beaded surface, the device is designed for both cemented and non-cemented press-fit use. This femoral component of the hip is indicated for use in patients with:

1 - Osteoarthritis

2 - Rheumatoid Arthritis

3 - Traumatic Arthritis and when the use of a more conservative procedure has failed or is unacceptable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 1997

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

Re: K971681
Trade Name: SMC Femoral Component
Regulatory Class: II
Product Codes: JDI and LPH
Dated: September 5, 1997
Received: September 12, 1997

Dear Dr. Serafin:

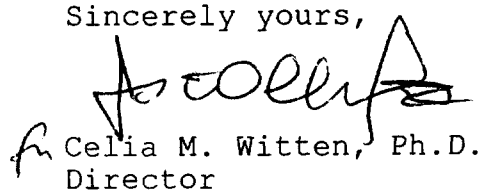
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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. 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. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, 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

K971681 DEC -4 1997

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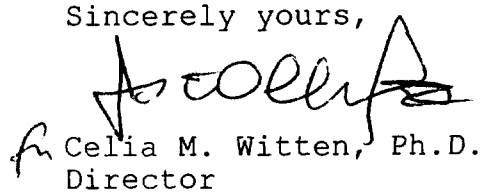

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k)Number(ifknown): K971681

Device Name: SMC FEMORAL COMPONENT

Indications For Use:

Osteoarthritis
Rheumatoid Arthritis
Traumatic Arthritis
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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971681

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format