DEC - 3 1998

K983452

SUMMARY OF SAFETY AND EFFECTIVENESS

SPONSOR: Biomet, Inc.
P. O. Box 587
Airport Industrial Park
Warsaw, Indiana 46581-0587

CONTACT PERSON: Julie K Ryan

DEVICE: Nelson Resurfacing Head

CLASSIFICATION NAME: Hip joint femoral (hemi-hip) metallic resurfacing prosthesis. 888.3400

INTENDED USE: The Nelson Resurfacing Head is indicated for use in:

a.) non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis
b.) rheumatoid arthritis

The Nelson Resurfaced Heads are intended for cemented application and for single use implantation.

DEVICE DESCRIPTION: This device is design to save the natural femur and provide a new surface on the femoral head for the hip to pivot on. The natural acetabulum will remain intact. The device will be manufactured out of cobalt-chrome-molybdenum. This device is intended for use with those who have had significant osteonecrosis of the femoral head. This procedure is limited to treating the diseased portion of the joint without violating the femoral canal with the stem of prosthesis.

POTENTIAL RISKS: The potential risk associated with this device is the same as with any joint resurfacing device. These include but are not limited to:

Fracture of the component
Cardiovascular disorders
Implant loosening /migration
Soft tissue imbalance
Deformity of the joint
Tissue growth failure
Delayed wound healing
Metal sensitivity
Bone fracture
Hematoma
Blood vessel damage
Nerve damage
Excessive wear
Infection
Dislocation

SUBSTANTIAL EQUIVALENCE: The Nelson Resurfacing Head is substantially equivalent to most head replacement devices on the market in overall function and design. Predicate devices are Wright Medical's Converse and BIOPRO's Ceramic TARA Femoral Resurfacing Component and THARIES.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 3 1998

Ms. Mary Verstynen
Regulatory Affairs
Biomet, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K983452
Nelson Resurfacing Head
Regulatory Class: II
Product Code: KXA
Dated: September 28, 1998
Received: September 30, 1998

Dear Ms. Verstynen:

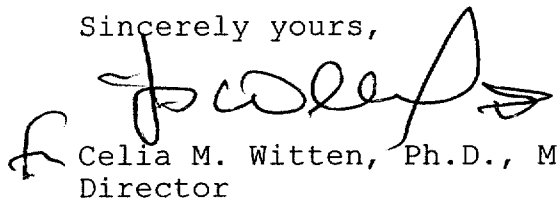
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



for 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: K983452
DEVICE NAME: The Nelson Resurfacing Head

The indications for use are:

a.) non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis
b.) rheumatoid arthritis

The Nelson Resurfacing Head is cemented femoral component and is a single use implant.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

or Over the Counter-Use ___
(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983452