

OCT 14 1999

SUMMARY OF SAFETY AND EFFECTIVENESS

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

Contact Person: Tracy J. Bickel
(219) 372-1761

Device(s): Maxim Knee System (Maxim PS w/ Retinacular Relief and Maxim PS V-II).

Classification: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (CFR 888.3560)

Device Description: The Maxim Knee femorals are composed of Co-Cr-Mo conforming to ASTM F-75 standards. The posterior stabilized femoral components provide stabilization in knees with soft tissue deficiencies. The devices achieve stability against posterior tibial subluxation through the posterior flange of the femoral component meeting a central polyethylene post on the tibial component. This configuration allows for minimal femoral femoral roll back and rotational instability. The modifications made to the anterior flange were the increase in height and the decrease in angle. The femoral augment holes are now threaded instead of unthreaded and material was removed from the anterior flange in the form of retinaculum relief.

There are six sizes available in both right and left configurations for the Maxim PS V-II femoral components as well as the Maxim PS w/ Retinacular Relief femoral components. The femoral articulation is the same as the Maximum Congruent Knee (K915132). The anatomic component design allows the surgeon to reconstruct the anatomic dimensions and kinematics of the natural femur. The femoral component has an Interlok finish for use in cemented applications.

The Maxim Knee System is indicated for:

- 1) Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, and/or traumatic arthritis where one or more compartments are involved.
- 2) Correction of varus, valgus, or posttraumatic deformity.
- 3) Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

K 9 9 3 1 5 9

Potential Risks: The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

- | | | |
|-----------------------------|----------------------------|----------------|
| Reaction to bone cement | Blood vessel damage | Bone fracture |
| Deformity of the joint | Soft tissue imbalance | Infection |
| Cardiovascular disease | Delayed wound healing | Hematoma |
| Fracture of the cement | Metal sensitivity | Dislocation |
| Implant loosening/migration | Fracture of the components | Excessive wear |
| Tissue growth failure | Nerve damage | |



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 14 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Tracy J. Bickel
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K993159
Maxim Knee System
Regulatory Class: II
Product Code: JWH
Dated: September 20, 1999
Received: September 21, 1999

Dear Ms. Bickel:

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.

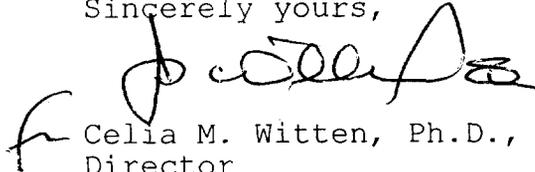
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Ms. Tracy J. Bickel

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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "W".

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): K993159

Device Name: Maxim Knee System

Indications for Use:

The Maxim Knee System is indicated for:

- 1) Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, and/or traumatic arthritis where one or more compartments are involved.
- 2) Correction of varus, valgus, or posttraumatic deformity.
- 3) Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

This device is for use with bone cement

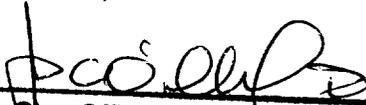
(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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) 000007
Division of General Restorative Devices
510(k) Number K993159