



CORPORATE HEADQUARTERS

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March 7, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: [Docket Number 00N-0018]

Orthopedic Devices; Reclassification of the Knee Joint Patellofemorotibial
Metal/Polymer Porous-Coated Uncemented Prosthesis and Knee Joint Femorotibial (Uni-
Compartmental) Metal/Polymer Porous-Coated Uncemented Prosthesis

Dear Sir or Madam:

Biomet agrees with the recommendation of the Orthopedic and Rehabilitation Devices
Panel that the above-referenced devices should be reclassified into Class II. We will
support a decision by FDA to approve the reclassification petition.

We thank the Agency for its effort and cooperation with the orthopedic industry and
medical professionals to reclassify these devices.

Sincerely yours,

Kenneth J. Beres, M.D.
Vice President,
Quality Assurance and Regulatory Affairs

00N-0018

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

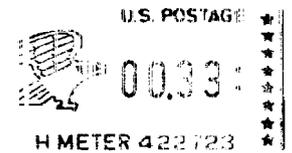
SHIPPING ADDRESS
Airport Industrial Park
Warsaw, IN 46580

OFFICE
219.267.6639

FAX
219.267.8137

E-MAIL
biomet@biomet.com

BIOMET[®] INC
CORPORATE HEADQUARTERS
P.O. Box 587
Warsaw, IN 46581-0587



DOCKETS MANAGEMENT BRANCH (HFZ-305)
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE, ROOM 1061
ROCKVILLE, MD 20852

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