



CORPORATE HEADQUARTERS

September 19, 2001

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

Docket Number: 99P-1864 (Comments)

Orthopedic and Rehabilitation Devices: Reclassification of the Hip Joint Metal/Polymer
Constrained Cemented or Uncemented Prosthesis

To Whom It May Concern:

Biomet has reviewed the Proposed Rule published in the September 6, 2001 *Federal Register*. Biomet agrees with the Agency's proposed action, and we believe it important that the device be reclassified as specified by the FDA in the Proposed Rule. We hope that the Final Rule will be published shortly after the close of the comment period on December 5, 2001.

In addition, Biomet agrees with the content of the guidance document for class II special controls that was published concurrently, and as companion document to this Proposed Rule.

Sincerely yours,

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

99P-1864

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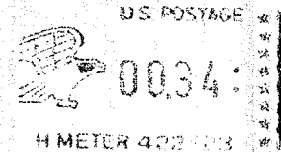
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