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January 17, 2001

Re: Your letter of November 14, 2000; Reclassification of the
Buechel-Pappas Unconstrained Ankle Prosthesis

Food and Drug Administration
Center Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850
Attn Jodi Anderson

Dear Ms Anderson:

We believe that the enclosed documentation meets all the requirements of Section 860.123 of the Act. If not, please let me know of any deficiencies as soon as possible.

Prompt action on this petition is urgently requested. Our original 510(k) application for this device was made in August 31, 1999. Such an implant is badly needed in this country. Further Dr. Feigal in the appeal hearing indicated that he would try to expedite the treatment of this matter.

Any help you can provide in moving this petition would be greatly appreciated.

Sincerely,

John Pappas

John Pappas
Regulatory Affairs

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F03/007-011-01109

Encl.
Cc. MJP

2004P-0457

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