



FILE COPY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

October 13, 2004

Michael J. Pappas, Ph.D.
President
Endotec, Incorporated
20 Valley Street
South Orange, NJ 07079

Dear Dr. Pappas:

Your petition requesting the Food and Drug Administration to reclassify the Buechel-Pappas Unconstrained Ankle Prosthesis from Class III to Class II was received by this office on 10/12/2004. It was assigned docket number 2004P-0457/CCP 1 and it was filed on 10/12/2004. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2004P-0457

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