



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

March 27, 2006

FILE COPY

Michael J. Pappas, Ph.D., P.E.
Endotec, Inc.
20 Valley Street, Suite 210
South Orange, NJ 07079

Dear Dr. Pappas:

Your petition requesting the Food and Drug Administration to reclassify a non-constrained, mobile-bearing ankle prosthesis was received by this office on 03/24/2006. It was assigned docket number 2004P-457/CCP 2 and it was filed on 03/24/2006. 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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