



APR 11 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Michael J. Pappas, Ph.D., P.E.
President,
Endotec, Incorporated
20 Valley Street,
Suite 210
South Orange, New Jersey 07079

Re: Citizen Petition – Docket Number 2004P-0457

Dear Dr. Pappas:

This is an interim response to your petition dated October 12, 2005, which was filed by the Food and Drug Administration (FDA) on October 13, 2005. In your petition, you ask that FDA reclassify the Buechel-Papas Unconstrained Ankle Prosthesis from Class III to Class II. Because of the complex issues presented by your petition, we are unable to issue a final response to you at this time. We expect to issue a final response in the near future.

If you have any questions about this interim response, please contact Myrna Hanna of our Regulations Staff at (240) 276-2347.

Sincerely yours,

Linda S. Kahan
Deputy Director
Center for Devices and
Radiological Health

2004P-0457

LET 3