



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

1293 '04 APR -E 19:36

MAR 26 2004

Michael J. Pappas, Ph.D., P.E.  
President  
Endotec  
50 South Center Street, Unit 10  
Orange, New Jersey 07050

RE: Docket No.- 2003P-0477

Dear Dr. Pappas:

This is an interim response to the petition filed by the Food and Drug Administration on October 8, 2003, regarding your request to revoke the Application Integrity Policy imposed on Endotec.

We are still considering the issues that you raise in your petition and we are unable to issue a final response at this time. We expect to issue a final response in the near future.

If you have any questions about this response, please call Laurie Lenkel at (301) 827-3390.

Sincerely yours,

Beverly Chernaik Rothstein  
Acting Deputy Director for  
Regulations and Policy  
Center for Devices and  
Radiological Health

✓ cc: Laurie Lenkel

2003P-0477

LET 1