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August 12, 2003

Ms. Heather Rosecrans
Food and Drug Administration
Rockville, MD 20857

RE: 510(M) REQUEST

Dear Ms. Rosecrans:

As per our telephone conversations today, I understand that my 510(m) request is futile since my device has not yet received a class II classification and that, to accomplish this, I must file a 510(k) application. Therefore, I wish to withdraw my application for a 510(m) exemption.

Thank you very much for your time and interest.

Yours truly,

Peter M. Rothenberg, M.D., M.A.