DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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January 24, 2003

Russel J. Thomsen, MD
11018 Peony Place NW
Silverdale, Washington 98383

Re: 02P-0338

Dear Dr. Thomsen:

This is an interim response to the petition you filed with the Food and Drug Administration on July 29, 2002 requesting the revocation of any regulation of prenatal listening devices otherwise known as doppler fetoscopes.

Your petition raises significant scientific considerations with regard to long-term exposure to continuous wave echoscopy, and FDA is currently undertaking a substantive review of those issues. In addition, FDA is examining the legal considerations surrounding the classification of these devices that your petition also identifies. FDA expects to issue a final response to your petition in the next few months.

If you have questions about this interim response, please contact Joseph M. Sheehan of our Regulations Staff at (301) 827-2974.

Sincerely,

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

02P-0338

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