DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 15 2001

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Greg Barrett.
President, Microvasive Endoscopy
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 07160

Docket No: 00P-1535

Dear Mr: Barrett,

This is an interim response to your petition, filed by the Food and Drug Administration (FDA) on September 22, 2000. In your petition, you request that FDA "amend 21 CFR §876.1075(b)(2) to limit the exemption from premarket notification requirements to two specified situations: 1) non-electric biopsy forceps which are labeled for single use and are not reprocessed, and 2) non-electric biopsy forceps which are originally designed and labeled to be reusable."

Because of the complex scientific and legal issues presented by your petition, we are unable to issue a final response to you at this time. We expect to be able to issue a final response to you in about a month.

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

Sincerely yours,

Linda S. Kahan

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

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