DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 23 2006

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Tierney Norsted, Ph. D., M.P.H.
Executive Vice President & Principal Advisor
Regulatory & Clinical Research Institute, Inc.
5353 Wayzata Boulevard, Suite 505
Minneapolis, MN 55416-1334

Re: Citizen Petition – Docket Number 2006P-0071/CCP1
Dated: February 9, 2006
Received: February 10, 2006

Dear Dr. Norsted,

This is an interim response to your petition dated February 9, 2006, which was filed by the Food and Drug Administration (FDA) on February 10, 2006. In your petition, you asked FDA to reclassify tissue adhesive devices (device classification code MPN) from Class III to Class II because, according to the petition, the application of general controls, such as the currently available guidance document entitled "Cyanoacrylate Tissue Adhesive for the Topical Approximation of Skin – Premarket Approval Applications (PMAs)" and conformance to existing ASTM performance standards will provide reasonable assurances of safety and effectiveness for such devices.

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 Scott McFarland of our Regulations Staff at (240) 276-2344.

Sincerely yours,

Linda S. Kahan

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

2006P-0071

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