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July 18, 2006

Food and Drug Administration
Center for Devices and Radiological Health
Regulations Staff (HFZ-215)
1350 Piccard Drive
Rockville, MD 20857

**Re: Amendment to 513(e) Petition For Reclassification
Tissue Adhesive For Soft Tissue Approximation
Docket Number: 2006P-0071/CCP1**

To Whom It May Concern,

This submission is provided to amend 513(e) Petition for Reclassification for Tissue Adhesives for Soft Tissue Approximation; Docket Number 2006P-0071/CCP1. In accordance with 21 CFR 860.123(b)(4), an original and two copies of this Amendment are enclosed.

Section 2.2 Intended Use of the Petition shall be amended to read:

"Topical cyanoacrylate tissue adhesives are intended for topical closure of surgical incisions, including laparoscopic incisions, and simple traumatic lacerations that have easily approximated skin edges. Topical cyanoacrylate tissue adhesives may be used in conjunction with, but not in place of, deep dermal stitches."

Please feel free to contact me at the numbers below should you have any comments or questions concerning this Petition for Reclassification.

Sincerely,

REGULATORY & CLINICAL RESEARCH INSTITUTE, INC.

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