May 15, 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 Amendment is provided in response to a telephone request from FDA Branch Chief, Stephen Rhodes, Plastic and Reconstructive Surgery Branch, received on May 12 2006, requesting copies of published literature sited in three sections of the Reclassification Petition for Tissue Adhesives Docket Number: 2006P-0071/CCP1. In accordance with 21 CFR 860.123(b)(4), an original and two copies of this Amendment are enclosed.

As requested, copies of representative published literature sited in Section 7.1 regarding a) wound closure, b) dehiscence, and c) cosmesis and listed in Tables 2, 3, and 4 of Attachment C are provided.

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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2006P-0071

AMD 1
Literature on Wound Closure:


Literature on Dehiscence:


2. Coulthard P et al.

3. Harold KL et al.


Literature on Wound Cosmesis:


5. Harold KL et al.


8. Maartense S, Bemelman WA, Dunker MS, de Lint C, Plierk EG, Busch OR, Gouma DJ. Randomized study of the effectiveness of closing laparoscopic trocar wounds with


11. van den Ende ED et al.