

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 cited 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 cited 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,

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AMD 1

Literature on Wound Closure:

1. Coulthard P, Worthington H, Esposito M, Elst M, Waes OJ. Tissue adhesives for closure of surgical incisions. *Cochrane Database Syst Rev*. 2004;(2):CD004287.
2. Harold KL, Goldstein SL, Nelms CD, Matthews BD, Sing RF, Kercher KW, Lincourt A, Heniford BT. Optimal closure method of five-millimeter trocar sites. *Am J Surg*. 2004 Jan;187(1):24-7.
3. Ong CC, Jacobsen AS, Joseph VT. Comparing wound closure using tissue glue versus subcuticular suture for pediatric surgical incisions: a prospective, randomised trial. *Pediatr Surg Int*. 2002 Sep;18(5-6):553-5. Epub 2002 Jun 14.
4. Singer AJ, Thode HC Jr. A review of the literature on octylcyanoacrylate tissue adhesive. *Am J Surg*. 2004 Feb;187(2):238-48.
5. Toriumi DM, Bagal AA. Cyanoacrylate tissue adhesives for skin closure in the outpatient setting. *Otolaryngol Clin North Am*. 2002 Feb;35(1):103-18, vi-vii.

Literature on Dehiscence:

1. Charters A. Wound glue: a comparative study of tissue adhesives. *Accid Emerg Nurs*. 2000 Oct;8(4):223-7
2. Coulthard P et al.
3. Harold KL et al.
4. Osmond MH, Quinn JV, Sutcliffe T, Jarmuske M, Klassen TP. A randomized, clinical trial comparing butylcyanoacrylate with octylcyanoacrylate in the management of selected pediatric facial lacerations. *Acad Emerg Med*. 1999 Mar;6(3):171-7.
5. van den Ende ED, Vriens PW, Allema JH, Breslau PJ. Adhesive bonds or percutaneous absorbable suture for closure of surgical wounds in children. Results of a prospective randomized trial. *J Pediatr Surg*. 2004 Aug;39(8):1249-51.

Literature on Wound Cosmesis:

1. Bernard L, Doyle J, Friedlander SF, Eichenfield LF, Gibbs NF, Cunningham BB. A prospective comparison of octyl cyanoacrylate tissue adhesive (dermabond) and suture for the closure of excisional wounds in children and adolescents. *Arch Dermatol*. 2001 Sep;137(9):1177-80.
2. Brown V. Laceration repair with tissue adhesive in children. *J Fam Pract*. 1997 May;44(5):445-6.
3. Bruns TB, Simon HK, McLario DJ, Sullivan KM, Wood RJ, Anand KJ. Laceration repair using a tissue adhesive in a children's emergency department. *Pediatrics*. 1996 Oct;98(4 Pt 1):673-5
4. Eaglstein WH, Sullivan TP, Giordano PA, Miskin BM. A liquid adhesive bandage for the treatment of minor cuts and abrasions. *Dermatol Surg*. 2002 Mar;28(3):263-7.
5. Harold KL et al.
6. Hollander JE, Singer AJ. Application of tissue adhesives: rapid attainment of proficiency. *Stony Brook Octylcyanoacrylate Study Group*. *Acad Emerg Med*. 1998 Oct;5(10):1012-7.
7. Kilic A, Ozdengil E. Skin graft fixation by applying cyanoacrylate without any complication. *Plast Reconstr Surg*. 2002 Jul;110(1):370-1.
8. Maartense S, Bemelman WA, Dunker MS, de Lint C, Pierik EG, Busch OR, Gouma DJ. Randomized study of the effectiveness of closing laparoscopic trocar wounds with

- octylcyanoacrylate, adhesive papertape or poliglecaprone. Br J Surg. 2002 Nov;89(11):1370-5.
9. Ozturan O, Miman MC, Aktas D, Oncel S. Butylcyanoacrylate tissue adhesive for columellar incision closure. J Laryngol Otol. 2001 Jul;115(7):535-40.
 10. Singer AJ, Hollander JE, Valentine SM, Turque TW, McCuskey CF, Quinn JV. Prospective, randomized, controlled trial of tissue adhesive (2-octylcyanoacrylate) vs standard wound closure techniques for laceration repair. Stony Brook Octylcyanoacrylate Study Group. Acad Emerg Med. 1998 Feb;5(2):94-9.
 11. van den Ende ED et al.