

K 900910

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Appendix C

**510(k) Summary of Safety and Effectiveness for
Indermil™ Dental**

LOCTITE 510(K) AS 1996-03-05 10:00 AM (Mar 4, 1996) (2) 35mm (1/2")

Submitter: Loctite Corporation
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Date summary was prepared: (Date of 510(k) clearance to be inserted)

Name of the device: Indermil™ Dental

Identification of predicate devices: Octylident® (CRX Medical, Raleigh, NC)
Iso-Dent® (Ellman International Mfg., Inc., Hewlett, NY)

Description of the device: Indermil™ Dental is liquid n-butyl 2-cyanoacrylate that cures in the presence of anions. Indermil™ Dental is sterilized by gamma radiation, and provided for use in high density polyethylene dispensers.

Intended Use: Indermil™ Dental is indicated for use as a dental cement for bonding dental materials, such as crowns, caps, and pins; or temporarily attaching a fiber to the surface of the tooth in a procedure to treat periodontal disease.

Comparison of device characteristics to predicate devices: Indermil™ Dental, Octylident®, and Iso-Dent® are all indicated for use in dental applications, including the bonding of dental materials, such as crowns, caps, and pins; or temporarily attaching a fiber to the surface of the tooth in a procedure to treat periodontal disease. The chemical compositions, n-butyl cyanoacrylate, octyl cyanoacrylate, and isobutyl cyanoacrylate, are equivalent, and test results further demonstrate that the two devices are equivalent in performance.

Conclusion: It is therefore concluded that Indermil™ Dental is substantially equivalent to Octylident® and to Iso-Dent®.