

Panel Questions

Reclassification Petition

Cyanoacrylate Tissue Adhesive for Topical Skin Approximation

1. Please discuss the risks to health presented by the petitioner for the cyanoacrylate tissue adhesive device for topical skin approximation. Please discuss any other risks to health for these devices that have not been identified.
2. Please discuss the adequacy of the proposed special controls for the risks identified by the petitioner and describe the special controls that you believe will address any additional risks identified by the Panel.
3. The intended use presented in the petition is: “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 discuss the adequacy of the proposed intended use.