

**K010583 AMBU GEL, HYDROGEL BURN DRESSING**May 25, 2001  
87 days to decisionK010583 · Product code: **MGQ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k010583/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound And Burn, Hydrogel W/drug And/or Biologic (MGQ)
Date received	Feb 27, 2001
Decision date	May 25, 2001
Days to decision	87 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Ambu, Inc.</b>
Location	Walker, MI, US
Contact	SANJAY PARIKH
510(k) history	33 submissions · 33 cleared · 1984-2005

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