

**K971309 UREA**Aug 1, 1997  
115 days to decisionK971309 · Product code: **CDQ** · Chemistry  
Source: <https://www.510kdatabase.net/k971309/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urease And Glutamic Dehydrogenase, Urea Nitrogen (CDQ)
Date received	Apr 8, 1997
Decision date	Aug 1, 1997
Days to decision	115 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Derma Media Lab., Inc.</b>
Location	Santa Fe Springs, CA, US
Contact	CHARLES C ALLAIN
510(k) history	18 submissions · 18 cleared · 1996-1997

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