

**K894538 QM300 ALPHA1-ACID GLYCOPROTEIN ANTIBODY  
PACK**Aug 4, 1989  
15 days to decisionK894538 · Product code: **DBN** · Immunology  
Source: <https://www.510kdatabase.net/k894538/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fc, Antigen, Antiserum, Control (DBN)
Date received	Jul 20, 1989
Decision date	Aug 4, 1989
Days to decision	15 days
Third-party review	No

**APPLICANT**

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Company	<b>Kallestad Diag, A Div. of Erbamont, Inc.</b>
Location	Chaska, MN, US
Contact	JAN NEBELSICK
510(k) history	58 submissions · 58 cleared · 1987-1991

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k894538/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 29, 2026