

**K010978 TINA-QUANT ALPHA-1 ANTITRYPSIN**May 18, 2001  
66 days to decisionK010978 · Product code: **DEM** · Immunology  
Source: <https://www.510kdatabase.net/k010978/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alpha-1-antitrypsin, Antigen, Antiserum, Control (DEM)
Date received	Mar 13, 2001
Decision date	May 18, 2001
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Rochdiag</b>
Location	Indianapolis, IN, US
Contact	KAY A TAYLOR
510(k) history	3 submissions · 3 cleared · 2001-2007

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