

**K964766 IMAGE IMMUNOCHEMISTRY SYSTEM  
ALPHA-1-ANTITRYPSIN (AAT)**Apr 25, 1997  
149 days to decisionK964766 · Product code: **DEM** · Immunology  
Source: <https://www.510kdatabase.net/k964766/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alpha-1-antitrypsin, Antigen, Antiserum, Control (DEM)
Date received	Nov 27, 1996
Decision date	Apr 25, 1997
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Beckman Instruments, Inc.</b>
Location	Mchenry, IL, US
Contact	ANNETTE HELLIE
Website	<a href="https://www.beckman.com">https://www.beckman.com</a>
510(k) history	281 submissions · 281 cleared · 1976-1998

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