

K965100 N-ASSAY TIA ALPHA-1-ANTITRYPSIN TEST KITJul 14, 1997
206 days to decisionK965100 · Product code: **DEM** · Immunology
Source: <https://www.510kdatabase.net/k965100/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alpha-1-antitrypsin, Antigen, Antiserum, Control (DEM)
Date received	Dec 20, 1996
Decision date	Jul 14, 1997
Days to decision	206 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Crestat Diagnostics, Inc.
Location	Portland, OR, US
Contact	MARY REES
510(k) history	29 submissions · 29 cleared · 1990-1998

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