

K053072 N ANTISERA TO HUMAN ALPHA1-ANTITRYPSINMar 28, 2006
147 days to decisionK053072 · Product code: **DEM** · Immunology
Source: <https://www.510kdatabase.net/k053072/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alpha-1-antitrypsin, Antigen, Antiserum, Control (DEM)
Date received	Nov 1, 2005
Decision date	Mar 28, 2006
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	KATHLEEN A DRAY-LYONS
510(k) history	343 submissions · 343 cleared · 1978-2010

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