

**K052819 VITROS CHEMISTRY PRODUCTS AAT REAGENT,
CALBRATOR KIT 99 AND AAT PERFORMANCE VERIFIERS I, II
AND III**Dec 23, 2005
80 days to decisionK052819 · Product code: **DEM** · Immunology
Source: <https://www.510kdatabase.net/k052819/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alpha-1-antitrypsin, Antigen, Antiserum, Control (DEM)
Date received	Oct 4, 2005
Decision date	Dec 23, 2005
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho-Clinical Diagnostics, Inc.
Location	Rochester, NY, US
Contact	Darlene J Phillips
510(k) history	106 submissions · 104 cleared · 1997-2025

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