

K062077 VITROS CHEMISTRY PRODUCTS AMPH REAGENTNov 22, 2006
124 days to decisionK062077 · Product code: **DKZ** · Chemistry
Source: <https://www.510kdatabase.net/k062077/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Jul 21, 2006
Decision date	Nov 22, 2006
Days to decision	124 days
Third-party review	No
Summary / Statement	Summary
Other names	CALIBRATOR KIT 26; FS CALIBRATOR 1; DAT PERFORMANCE VERIFIERS

APPLICANT

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

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