

**K062285 VITROS CHEMISTRY PRODUCTS BENZ REAGENT,
CALBRATOR KIT 26, FS CALBRATOR 1 AND DAT
PERFORMANCE VERIFIERS I, II, III, IV**Dec 22, 2006
137 days to decisionK062285 · Product code: **JXM** · Chemistry
Source: <https://www.510kdatabase.net/k062285/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Benzodiazepine (JXM)
Date received	Aug 7, 2006
Decision date	Dec 22, 2006
Days to decision	137 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k062285/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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