

K052867 VITROS CHEMISTRY PRODUCTS DTIBC REAGENTDec 23, 2005
73 days to decisionK052867 · Product code: **JMO** · Chemistry
Source: <https://www.510kdatabase.net/k052867/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ferrozine (colorimetric) Iron Binding Capacity (JMO)
Date received	Oct 11, 2005
Decision date	Dec 23, 2005
Days to decision	73 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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