

**K033300 VITROS IMMUNODIAGNOSTIC PRODUCTS
MYOGLOBIN REAGENT PACK**Nov 5, 2003
22 days to decisionK033300 · Product code: **DDR** · Chemistry
Source: <https://www.510kdatabase.net/k033300/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Myoglobin, Antigen, Antiserum, Control (DDR)
Date received	Oct 14, 2003
Decision date	Nov 5, 2003
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary
Other names	CALIBRATORS; RANGE VERIFIERS

APPLICANT

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

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