

**K973331 VITROS IMMUNODIAGNOSTIC PRODUCTS FERRITIN
REAGENT PACK (GEM.1340), FERRITIN CALIBRATORS
(GEM.C340)**Oct 22, 1997
48 days to decisionK973331 · Product code: **DBF** · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ferritin, Antigen, Antiserum, Control (DBF)
Date received	Sep 4, 1997
Decision date	Oct 22, 1997
Days to decision	48 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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