

**K001885 VITROS CHEMISTRY PRODUCTS BUN/UREA SLIDES
AND VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 1**Jul 20, 2000
29 days to decisionK001885 · Product code: **CDN** · Chemistry
Source: <https://www.510kdatabase.net/k001885/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Urease, Photometric, Urea Nitrogen (CDN)
Date received	Jun 21, 2000
Decision date	Jul 20, 2000
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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