

K190326 VITROS XT Chemistry Products UREA-CREA SlidesMar 14, 2019
29 days to decisionK190326 · Product code: **CDN** · Chemistry
Source: <https://www.510kdatabase.net/k190326/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urease, Photometric, Urea Nitrogen (CDN)
Date received	Feb 13, 2019
Decision date	Mar 14, 2019
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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