

K182063 VITROS Chemistry Products CRBM Slides, VITROS Chemistry Products CREA Slides, VITROS Chemistry Products TBIL Slides, VITROS XT 7600 Integrated SystemOct 30, 2018
90 days to decisionK182063 · Product code: JFY · Chemistry
Source: <https://www.510kdatabase.net/k182063/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Creatinine (JFY)
Date received	Aug 1, 2018
Decision date	Oct 30, 2018
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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