

K191316 VITROS XT Chemistry Products ALB-TP SlidesJun 7, 2019
23 days to decisionK191316 · Product code: **CIX** · Chemistry
Source: <https://www.510kdatabase.net/k191316/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bromocresol Green Dye-binding, Albumin (CIX)
Date received	May 15, 2019
Decision date	Jun 7, 2019
Days to decision	23 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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