

K011720 OLYMPUS AU5400 CLINICAL CHEMISTRY ANALYZERJun 25, 2001
21 days to decisionK011720 · Product code: **CIX** · Chemistry
Source: <https://www.510kdatabase.net/k011720/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Bromocresol Green Dye-binding, Albumin (CIX)
Date received	Jun 4, 2001
Decision date	Jun 25, 2001
Days to decision	21 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Olympus America, Inc.
Location	Lake Success, NY, US
Contact	MICHAEL CAMPBELL
510(k) history	149 submissions · 149 cleared · 1994-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011720/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 18, 2026