

**K013332 LINICAL PROTEIN I CALIBRATION VERIFIERS
LEVELS A=E FOR BECKMAN COULTER IMAGE**Nov 20, 2001
42 days to decisionK013332 · Product code: JJY · Immunology
Source: <https://www.510kdatabase.net/k013332/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Oct 9, 2001
Decision date	Nov 20, 2001
Days to decision	42 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Cliniqa Corporation
Location	Fallbrook, CA, US
Contact	CAROL RUGGIERO
510(k) history	36 submissions · 36 cleared · 2001-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013332/> 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 June 9, 2026