

**K964695 IMAGE IMMUNOCHEMISTRY SYSTEM ALBUMIN
(ALB) REAGENT**Apr 29, 1997
158 days to decisionK964695 · Product code: **DCF** · Immunology
Source: <https://www.510kdatabase.net/k964695/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Albumin, Antigen, Antiserum, Control (DCF)
Date received	Nov 22, 1996
Decision date	Apr 29, 1997
Days to decision	158 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Beckman Instruments, Inc.
Location	Mchenry, IL, US
Contact	FRANK MARTE
Website	https://www.beckman.com
510(k) history	281 submissions · 281 cleared · 1976-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964695/> 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 22, 2026