

K053553 NYCOCARD U-ALBUMIN AND U-ALBUMIN CONTROLMar 9, 2006
79 days to decisionK053553 · Product code: **DCF** · Chemistry
Source: <https://www.510kdatabase.net/k053553/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Albumin, Antigen, Antiserum, Control (DCF)
Date received	Dec 20, 2005
Decision date	Mar 9, 2006
Days to decision	79 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Polymedco, Inc.
Location	Cortlandt Manor, NY, US
Contact	HELEN LANDRICH
510(k) history	19 submissions · 19 cleared · 1992-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k053553/> 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 18, 2026