

K970302 APO-TEK LP(A)Nov 10, 1997
287 days to decisionK970302 · Product code: **DFC** · Immunology
Source: <https://www.510kdatabase.net/k970302/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lipoprotein, Low-density, Antigen, Antiserum, Control (DFC)
Date received	Jan 27, 1997
Decision date	Nov 10, 1997
Days to decision	287 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Perimmune, Inc.
Location	Rockville, MD, US
Contact	PETER A MANILLA
510(k) history	2 submissions · 2 cleared · 1997-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k970302/> 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 29, 2026