

K051218 MODIFICATION TO: UNICAP SPECIFIC IGE

Jun 9, 2005
 28 days to decision

K051218 · Product code: **DHB** · Immunology
 Source: <https://www.510kdatabase.net/k051218/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	May 12, 2005
Decision date	Jun 9, 2005
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pharmacia Diagnostics AB
Location	Portae, MI, US
Contact	MARTIN R MANN
510(k) history	2 submissions · 2 cleared · 2005-2006

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k051218/> 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