

**K013135 IMMUNLITE 2000 ALLERGEN-SPECIFIC IGE AND MIXED ALLERGEN PANELS, MODEL L2KUN6 (600 TESTS)**

Oct 19, 2001  
30 days to decision

K013135 · Product code: **DHB** · Immunology  
Source: <https://www.510kdatabase.net/k013135/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Sep 19, 2001
Decision date	Oct 19, 2001
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Diagnostic Products Corp.</b>
Location	Mchenry, IL, US
Contact	EDWARD M LEVINE
510(k) history	321 submissions · 321 cleared · 1976-2006

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k013135/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 20, 2026