

**K914850 CHEMILUMINESCENT SYSTEM ALLERGAN SPECIFIC  
IGE**Dec 9, 1991  
42 days to decisionK914850 · Product code: **DHB** · Immunology  
Source: <https://www.510kdatabase.net/k914850/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Oct 28, 1991
Decision date	Dec 9, 1991
Days to decision	42 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Mast Immunosystems</b>
Location	Mchenry, IL, US
Contact	ALEX MONTE
510(k) history	13 submissions · 13 cleared · 1983-1994

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k914850/> 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 30, 2026