

**K000755 RHIGENE MESACUP2 TEST- SM**May 9, 2000  
62 days to decisionK000755 · Product code: **LKP** · Immunology  
Source: <https://www.510kdatabase.net/k000755/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-sm Antibody, Antigen And Control (LKP)
Date received	Mar 8, 2000
Decision date	May 9, 2000
Days to decision	62 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Rhigene, Inc.</b>
Location	Des Plaines, IL, US
Contact	DAVE KOLESAR
510(k) history	15 submissions · 15 cleared · 2000-2004

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k000755/> 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 29, 2026