

K000752 RHIGENE MESACUP2 TEST- RNPMay 9, 2000
62 days to decisionK000752 · Product code: **LKO** · Immunology
Source: <https://www.510kdatabase.net/k000752/>**SUBMISSION DETAILS**

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

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k000752/> 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