

K000749 RHIGENE MESACUP2 TEST- SSAMay 9, 2000
62 days to decisionK000749 · Product code: **LLL** · Immunology
Source: <https://www.510kdatabase.net/k000749/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Extractable Antinuclear Antibody, Antigen And Control (LLL) |
| 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 |

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