

**K851099 IGM RHEUMATOID FACTOR TEST KIT**Apr 25, 1985  
37 days to decisionK851099 · Product code: **DHR** · Immunology  
Source: <https://www.510kdatabase.net/k851099/>**SUBMISSION DETAILS**

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|                       |                                       |
|-----------------------|---------------------------------------|
| Decision              | Substantially Equivalent (Cleared)    |
| Submission type       | Traditional                           |
| Device classification | System, Test, Rheumatoid Factor (DHR) |
| Date received         | Mar 19, 1985                          |
| Decision date         | Apr 25, 1985                          |
| Days to decision      | 37 days                               |
| Third-party review    | No                                    |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Breit Laboratories, Inc.</b>       |
| Location       | Mchenry, IL, US                       |
| Contact        | LEROY L KONDO                         |
| 510(k) history | 5 submissions · 5 cleared · 1983-1985 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k851099/>; 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