

**K903037 LUPO-TEST REAGENT**Dec 17, 1990  
159 days to decisionK903037 · Product code: **GIR** · Hematology  
Source: <https://www.510kdatabase.net/k903037/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Russel Viper Venom (GIR)
Date received	Jul 11, 1990
Decision date	Dec 17, 1990
Days to decision	159 days
Third-party review	No

**APPLICANT**

---

Company	<b>Gradipore , Ltd.</b>
Location	Pyrmont, AU
Contact	RHONDA SMYTH
510(k) history	4 submissions · 4 cleared · 1990-2000

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k903037/>; 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 28, 2026