

**K993332 GRADIPLASMA LA HIGH, GRADIPLASMA LA LOW
MODELS LAHP-1, LAHP-05, LALP-1, LALP-05**Feb 16, 2000
135 days to decisionK993332 · Product code: **GGC** · Hematology
Source: <https://www.510kdatabase.net/k993332/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Control, Plasma, Abnormal (GGC)
Date received	Oct 4, 1999
Decision date	Feb 16, 2000
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gradipore , Ltd.
Location	Pymont, AU
Contact	RHONDA PILGRIM
510(k) history	4 submissions · 4 cleared · 1990-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k993332/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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