

K983914 REAADS MONOCLONAL FREE PROTEIN S ANTIGEN TEST KIT

Dec 22, 1998
48 days to decision

K983914 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k983914/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Nov 4, 1998
Decision date	Dec 22, 1998
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Corgenix, Inc.
Location	Westminster, CO, US
Contact	NANCI DEXTER
510(k) history	23 submissions · 23 cleared · 1998-2008

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Device record: <https://www.510kdatabase.net/k983914/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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