

K042762 PEFAKIT APC-R FACTOR V LEIDENDec 22, 2004
78 days to decisionK042762 · Product code: **GGW** · Hematology
Source: <https://www.510kdatabase.net/k042762/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Partial Thromboplastin (GGW)
Date received	Oct 5, 2004
Decision date	Dec 22, 2004
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pentapharm , Ltd.
Location	Washington, DC, US
Contact	M. ELISABETH BIERMAN
510(k) history	2 submissions · 2 cleared · 2004-2004

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