

**K945940 COATEST(R) APC(TM) RESISTANCE**Aug 7, 1995  
245 days to decisionK945940 · Product code: **GGW** · Hematology  
Source: <https://www.510kdatabase.net/k945940/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Partial Thromboplastin (GGW)
Date received	Dec 5, 1994
Decision date	Aug 7, 1995
Days to decision	245 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Axis-Shield Doc AS</b>
Location	San Diego, CA, US
Contact	RONALD G LEONARDI
510(k) history	1 submissions · 1 cleared · 1995-1995

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