

K980885 SHIELD ACTIVATED FACTOR XII (ELISA) ASSAYAug 21, 1998
165 days to decisionK980885 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k980885/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Mar 9, 1998
Decision date	Aug 21, 1998
Days to decision	165 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Shield Diagnostics, Ltd.
Location	Scotland, KN
Contact	EILEEN MCCAFFERTY
510(k) history	27 submissions · 27 cleared · 1990-2000

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