

**K982879 SHIELD DIASTAT ANTI-B2 GLYCOPROTEIN 1 IGG
(ELISA) ASSAY**

Oct 15, 1998
62 days to decision

K982879 · Product code: **MSV** · Immunology
Source: <https://www.510kdatabase.net/k982879/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System,test,antibodies,b2 - Glycoprotein I (b2 - Gpi) (MSV)
Date received	Aug 14, 1998
Decision date	Oct 15, 1998
Days to decision	62 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k982879/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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