

**K031177 DIASTAT ANTI-B2 GLYCOPROTEIN 1 IGM, MODEL
FBGP 100M**Jun 19, 2003
66 days to decisionK031177 · Product code: **MSV** · Immunology
Source: <https://www.510kdatabase.net/k031177/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System,test,antibodies,b2 - Glycoprotein I (b2 - Gpi) (MSV) |
| Date received | Apr 14, 2003 |
| Decision date | Jun 19, 2003 |
| Days to decision | 66 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Axis-Shield Diagnostics, Ltd. |
| Location | Dundee, GB |
| Contact | EILEEN MCCAFFERTY |
| Website | http://www.axis-shield.com/ |
| 510(k) history | 24 submissions · 24 cleared · 2002-2026 |

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