

**K053012 FIDIS VASCULITIS, MODEL MX007**Mar 2, 2006  
127 days to decisionK053012 · Product code: **MOB** · Immunology  
Source: <https://www.510kdatabase.net/k053012/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Oct 26, 2005
Decision date	Mar 2, 2006
Days to decision	127 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Biomedical Diagnostics (Bmd) SA</b>
Location	Marne La Vallee Cedex 2, FR
Contact	CHRISTELLE COURIVAUD
510(k) history	10 submissions · 10 cleared · 2005-2010

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