

**K100917 FIDIS VASCULITIS ASSAY KIT AND ANALYZER AND
CARIS SYSTEM**Nov 3, 2010
215 days to decisionK100917 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k100917/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Apr 2, 2010
Decision date	Nov 3, 2010
Days to decision	215 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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