

K070458 MODIFICATION TO FIDIS VASCULITIS, MODEL MX007Dec 21, 2007
308 days to decisionK070458 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k070458/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Feb 16, 2007
Decision date	Dec 21, 2007
Days to decision	308 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k070458/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 20, 2026