FDA 510(k) Premarket Notification

K070458 MODIFICATION TO FIDIS VASCULITIS, MODEL MX007

CLEARED

Dec 21, 2007
308 days to decision

K070458 · 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