

**K061794 FIDIS TM THYRO, MODEL MX002**Nov 21, 2006  
148 days to decisionK061794 · Product code: **JZO** · Immunology  
Source: <https://www.510kdatabase.net/k061794/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Thyroid Autoantibody (JZO)
Date received	Jun 26, 2006
Decision date	Nov 21, 2006
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary

**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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061794/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 20, 2026