

**K983553 ANTI-TG IGG ELISA TEST SYSTEM**Dec 7, 1998  
59 days to decisionK983553 · Product code: **JZO** · Immunology  
Source: <https://www.510kdatabase.net/k983553/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Thyroid Autoantibody (JZO)
Date received	Oct 9, 1998
Decision date	Dec 7, 1998
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Columbia Bioscience, Inc.</b>
Location	Frederick, MD, US
Contact	NORMAN JENKINS
510(k) history	13 submissions · 13 cleared · 1996-1999

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