

**K033454 BRAHMS DIAGNOSTICA LUMITEST TRAK HUMAN**Mar 22, 2004  
144 days to decisionK033454 · Product code: **JZO** · Immunology  
Source: <https://www.510kdatabase.net/k033454/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Thyroid Autoantibody (JZO)
Date received	Oct 30, 2003
Decision date	Mar 22, 2004
Days to decision	144 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Brahms Diagnostica, LLC</b>
Location	Norcross, GA, US
Contact	WILLIAM G FRANK
510(k) history	6 submissions · 6 cleared · 1999-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k033454/> 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 29, 2026