

**K904224 NOVA LITE TM THYROID**

Oct 15, 1990  
32 days to decision

K904224 · Product code: **JZO** · Immunology  
Source: <https://www.510kdatabase.net/k904224/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Thyroid Autoantibody (JZO)
Date received	Sep 13, 1990
Decision date	Oct 15, 1990
Days to decision	32 days
Third-party review	No

**APPLICANT**

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Company	<b>Inova Diagnostics, Inc.</b>
Location	San Diego, CA, US
Contact	BRY S C MYERS
Website	<a href="https://www.inovadx.com">https://www.inovadx.com</a>
510(k) history	138 submissions · 136 cleared · 1988-2026

Siemens Healthcare Diagnostics, Inc. is a leading diagnostic device manufacturer based in New York. The company specializes in laboratory diagnostics and clinical chemistry solutions. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2008. Chemistry devices and immunology assays represent the core focus of its regulatory portfolio. The latest FDA 510(k) clearance in 2026 reflects continued active development and market engagement. Recent cleared devices include automated chemistry analyzers, immunoassay systems, and special...

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