

**K954256 ANTI-TPO**Nov 27, 1995  
83 days to decisionK954256 · Product code: **JNL** · Immunology  
Source: <https://www.510kdatabase.net/k954256/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunochemical, Thyroglobulin Autoantibody (JNL)
Date received	Sep 5, 1995
Decision date	Nov 27, 1995
Days to decision	83 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Biomerica, Inc.</b>
Location	Newport Beach, CA, US
Contact	PERRY RUCKER
Website	<a href="http://www.biomerica.com">http://www.biomerica.com</a>
510(k) history	10 submissions · 10 cleared · 1991-2023

Biomerica, Inc. is a global biomedical technology company developing, manufacturing, and marketing advanced in-vitro diagnostic products. Headquartered in Irvine, California, the company operates FDA and CE registered manufacturing facilities in California and Mexico, specializing in gastrointestinal and inflammatory disease diagnostics. Biomerica has received FDA 510(k) clearances from total submissions since 1991. The company's cleared devices span chemistry, microbiology, and immunology categories, including pregnancy tests, thyroid function assays, H. pylori detection...

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