

**K962216 TSH (MICROWELL) ELISA**Sep 19, 1996  
101 days to decisionK962216 · Product code: **JLW** · Chemistry  
Source: <https://www.510kdatabase.net/k962216/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Jun 10, 1996
Decision date	Sep 19, 1996
Days to decision	101 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Biomerica, Inc.</b>
Location	Newport Beach, CA, US
Contact	JAY SINGH
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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