

**K813645 MICROMEDIC HTSH RIA KIT**Jan 22, 1982  
22 days to decisionK813645 · Product code: **JLW** · Chemistry  
Source: <https://www.510kdatabase.net/k813645/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Dec 31, 1981
Decision date	Jan 22, 1982
Days to decision	22 days
Third-party review	No

**APPLICANT**

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Company	<b>Micromedic Systems</b>
Location	Walker, MI, US
Website	<a href="https://www.micromedic.com">https://www.micromedic.com</a>
510(k) history	42 submissions · 42 cleared · 1976-1993

Micromedic Systems is a medical device manufacturer based in Walker, US. The company specialized in diagnostic and laboratory instrumentation. Micromedic Systems received FDA 510(k) clearances from total submissions, with no denied submissions on record. The company's regulatory focus centered on Chemistry devices, which represented 81% of all submissions. Clearances span from 1976 to 1993, establishing a significant historical presence in clinical laboratory testing. The company's cleared device portfolio included immunoassay kits for thyroid and reproductive hormone tes...

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