

**K871505 AUTOPAK NEONATAL TSH MONOCLONAL IRMA KIT**May 26, 1987  
39 days to decisionK871505 · Product code: **JLW** · Chemistry  
Source: <https://www.510kdatabase.net/k871505/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Apr 17, 1987
Decision date	May 26, 1987
Days to decision	39 days
Third-party review	No

**APPLICANT**

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Company	<b>Micromedic Systems</b>
Location	Walker, MI, US
Contact	DEBORAH L LINDEMUTH
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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