

**K840188 MICROMEDIC LH & FSH RIA KIT**Mar 23, 1984  
65 days to decisionK840188 · Product code: **CEP** · Chemistry  
Source: <https://www.510kdatabase.net/k840188/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Jan 18, 1984
Decision date	Mar 23, 1984
Days to decision	65 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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