

**K831264 BHCg RIA KIT**Jun 8, 1983  
51 days to decisionK831264 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k831264/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Apr 18, 1983
Decision date	Jun 8, 1983
Days to decision	51 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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