

**K820376 MICROMEDIC SYSTEMS ISOFLEX**Mar 16, 1982  
35 days to decisionK820376 · Product code: **JJJ** · Radiology  
Source: <https://www.510kdatabase.net/k820376/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter (beta, Gamma) For Clinical Use (JJJ)
Date received	Feb 9, 1982
Decision date	Mar 16, 1982
Days to decision	35 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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