

**K923643 MEDICOOL**Mar 31, 1993  
253 days to decisionK923643 · Product code: **ILO** · Physical Medicine  
Source: <https://www.510kdatabase.net/k923643/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pack, Hot Or Cold, Water Circulating (ILO)
Date received	Jul 21, 1992
Decision date	Mar 31, 1993
Days to decision	253 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Micromedic Systems</b>
Location	Walker, MI, US
Contact	TOMAS E DUNN
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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