

K821678 AUTOPAK ESTRIOL TEST DELIVERY SYSTEMJun 24, 1982
16 days to decisionK821678 · Product code: **CGI** · Chemistry
Source: <https://www.510kdatabase.net/k821678/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Estriol (CGI)
Date received	Jun 8, 1982
Decision date	Jun 24, 1982
Days to decision	16 days
Third-party review	No

APPLICANT

Company	Micromedic Systems
Location	Walker, MI, US
Website	https://www.micromedic.com
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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