

K781086 INSULIN AUTOPAKAug 14, 1978
46 days to decisionK781086 · Product code: **CFP** · Toxicology
Source: <https://www.510kdatabase.net/k781086/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Immunoreactive Insulin (CFP)
Date received	Jun 29, 1978
Decision date	Aug 14, 1978
Days to decision	46 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...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k781086/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 22, 2026