

K791325 AUTOPAK 12 DIGOXIN TEST DELIVERY SYSTEMAug 16, 1979
35 days to decisionK791325 · Product code: **DPO** · Toxicology
Source: <https://www.510kdatabase.net/k791325/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Digoxin (125-i), Rabbit Antibody, Coated Tube Sep. (DPO)
Date received	Jul 12, 1979
Decision date	Aug 16, 1979
Days to decision	35 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...
