

K832462 AUTOPAK NEONATAL TSH RIA KITSep 12, 1983
48 days to decisionK832462 · Product code: **JLW** · Chemistry
Source: <https://www.510kdatabase.net/k832462/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Jul 26, 1983
Decision date	Sep 12, 1983
Days to decision	48 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...
