

K950292 FOLATE ASSAY FOR THE TECHNICON IMMUNO 1 SYSTEM, IN VITRO DIAGNOSTIC SYSTEMMay 2, 1995
97 days to decisionK950292 · Product code: **CGN** · Chemistry
Source: <https://www.510kdatabase.net/k950292/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Acid, Folic, Radioimmunoassay (CGN)
Date received	Jan 25, 1995
Decision date	May 2, 1995
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Miles, Inc.
Location	Tarrytown, NY, US
Contact	GABRIEL J MURACA, JR.
510(k) history	11 submissions · 11 cleared · 1993-1995

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k950292/> 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 June 28, 2026