

K903034 RENALYZER PRX 90Mar 13, 1991
245 days to decisionK903034 · Product code: **CGL** · Chemistry
Source: <https://www.510kdatabase.net/k903034/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Ion Based, Enzymatic, Creatinine (CGL)
Date received	Jul 11, 1990
Decision date	Mar 13, 1991
Days to decision	245 days
Third-party review	No

APPLICANT

Company	Swedish Trade Council USA
Location	Chicago, IL, US
Contact	ANDERS SJOBERG
510(k) history	2 submissions · 2 cleared · 1989-1991

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k903034/>; 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 July 2, 2026