

K823128 ADVANCE EMIT CAD PROCAINAMIDE ASSAYNov 29, 1982
35 days to decisionK823128 · Product code: **LAR** · Chemistry
Source: <https://www.510kdatabase.net/k823128/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Procainamide (LAR)
Date received	Oct 25, 1982
Decision date	Nov 29, 1982
Days to decision	35 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	Syva Co.
Location	Mchenry, IL, US
510(k) history	448 submissions · 447 cleared · 1976-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k823128/> 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 19, 2026