

K833623 MODIF. OF EMIT CAD DISOPYRAMIDE ASSAYDec 8, 1983
55 days to decisionK833623 · Product code: **KLR** · Toxicology
Source: <https://www.510kdatabase.net/k833623/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Lidocaine (KLR)
Date received	Oct 14, 1983
Decision date	Dec 8, 1983
Days to decision	55 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/k833623/> 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