

K915003 EMIT CALIBRATOR LEVEL 1(CUTOFF)/LEVEL 2(HIGH)Nov 29, 1991
22 days to decisionK915003 · Product code: **DKB** · Toxicology
Source: <https://www.510kdatabase.net/k915003/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrators, Drug Mixture (DKB)
Date received	Nov 7, 1991
Decision date	Nov 29, 1991
Days to decision	22 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k915003/> 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