

**K910527 EMIT CONVENIENCE PACK FOR THE COBAS MIRA
PRIMIDONE**Mar 14, 1991
35 days to decisionK910527 · Product code: **DJD** · Toxicology
Source: <https://www.510kdatabase.net/k910527/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Primidone (DJD)
Date received	Feb 7, 1991
Decision date	Mar 14, 1991
Days to decision	35 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k910527/> 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