FDA 510(k) Premarket Notification

K842676 EMIT D.A.U. METHADONE ASSAY

CLEARED

Sep 26, 1984
78 days to decision

K842676 · Product code: **DJR** · Toxicology
Source: https://www.510kdatabase.net/k842676/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Methadone (DJR)
Date received	Jul 10, 1984
Decision date	Sep 26, 1984
Days to decision	78 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.net
Device record: https://www.510kdatabase.net/k842676/ 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