FDA 510(k) Premarket Notification

K902580 EMIT(R) II BARBITURATE ASSAY

CLEARED

Jul 19, 1990
38 days to decision

K902580 · Product code: **DIS** · Toxicology
Source: https://www.510kdatabase.net/k902580/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Barbiturate (DIS)
Date received	Jun 11, 1990
Decision date	Jul 19, 1990
Days to decision	38 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.net
Device record: https://www.510kdatabase.net/k902580/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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