FDA 510(k) Premarket Notification

K843556 EMIT D.A.U. COCAINE ASSAY

CLEARED

Oct 5, 1984
25 days to decision

K843556 · Product code: **DIO** · Toxicology
Source: https://www.510kdatabase.net/k843556/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Sep 10, 1984
Decision date	Oct 5, 1984
Days to decision	25 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/k843556/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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