FDA 510(k) Premarket Notification

K000350 SCREENERS COCAINE TEST

CLEARED

Apr 11, 2000
68 days to decision

K000350 · Product code: **DIO** · Toxicology
Source: https://www.510kdatabase.net/k000350/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Feb 3, 2000
Decision date	Apr 11, 2000
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary
Other names	DRUGSCREEN DIP COCAINE TEST

APPLICANT

Company	**Drug Detection Devices, Ltd.**
Location	Alpharetta, GA, US
Contact	PATRICK BEENTJES
510(k) history	8 submissions · 8 cleared · 1999-2000

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k000350/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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