FDA 510(k) Premarket Notification

K914533 MICRO EIA FOR COCAINE METABOLITES

CLEARED

Dec 10, 1991
60 days to decision

K914533 · Product code: **DIO** · Toxicology
Source: https://www.510kdatabase.net/k914533/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Oct 11, 1991
Decision date	Dec 10, 1991
Days to decision	60 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Microdiagnostics, Inc.**
Location	Laguna Niguel, CA, US
Contact	ROY CHUNG
510(k) history	10 submissions · 10 cleared · 1991-2001

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k914533/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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