

**K001197 COCAINE METABOLITE INTERCEPT MICRO-PLATE
EIA**

May 11, 2000
30 days to decision

K001197 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k001197/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Apr 11, 2000
Decision date	May 11, 2000
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	OraSure Technologies, Inc.
Location	Bethlehem, PA, US
Contact	R. SAM NIEDBALA
510(k) history	30 submissions · 29 cleared · 1996-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k001197/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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