

K972384 AQ ONE STEP COCAINE TESTAug 6, 1997
41 days to decisionK972384 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k972384/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Jun 26, 1997
Decision date	Aug 6, 1997
Days to decision	41 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Bionike Laboratories, Inc.
Location	Sunnyvale, CA, US
Contact	JANIS FREESTONE
510(k) history	6 submissions · 6 cleared · 1995-1999

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