FDA 510(k) Premarket Notification

K020771 ACON ONE STEP DRUG SCREEN TEST CARD

CLEARED

May 15, 2002
68 days to decision

K020771 · Product code: **DIO** · Toxicology
Source: https://www.510kdatabase.net/k020771/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Mar 8, 2002
Decision date	May 15, 2002
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**ACON Laboratories, Inc.**
Location	San Diego, CA, US
Contact	EDWARD TUNG
Website	http://www.aconlabs.com/
510(k) history	85 submissions · 85 cleared · 1998-2025

ACON Laboratories, Inc. is a global medical device manufacturer headquartered in San Diego, California. The company develops and manufactures diagnostic and point-of-care testing devices for hospitals, clinical laboratories, physician offices, blood banks, pharmacies, and veterinary clinics. ACON operates in over 130 countries and maintains FDA-registered manufacturing facilities with ISO 13485 certification. ACON has received FDA 510(k) clearances from total submissions since 1998, with no denied submissions. The company specializes in chemistry devices, including blood ...