FDA 510(k) Premarket Notification

K111221 MISSION U500 URINE ANALYZER

CLEARED

Jan 18, 2012
261 days to decision

K111221 · Product code: **JIO** · Chemistry
Source: https://www.510kdatabase.net/k111221/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Blood, Occult, Colorimetric, In Urine (JIO)
Date received	May 2, 2011
Decision date	Jan 18, 2012
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**ACON Laboratories, Inc.**
Location	San Diego, CA, US
Contact	QIYI XIE
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 ...