FDA 510(k) Premarket Notification

K012252 QUIK-CHECK OVULATION PREDICTOR

CLEARED

Aug 24, 2001
37 days to decision

K012252 · Product code: **CEP** · Chemistry
Source: https://www.510kdatabase.net/k012252/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Jul 18, 2001
Decision date	Aug 24, 2001
Days to decision	37 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**ACON Laboratories, Inc.**
Location	San Diego, CA, US
Contact	FRAN WHITE
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 ...