FDA 510(k) Premarket Notification

CLEARED

K232715 Distinct® Digital Pregnancy Test

May 31, 2024
269 days to decision

K232715 · Product code: **LCX** · Chemistry
Source: https://www.510kdatabase.net/k232715/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Sep 5, 2023
Decision date	May 31, 2024
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

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 ...

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	James E. Mullally, PhD.

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov