FDA 510(k) Premarket Notification

K203272 Alltest Pregnancy Rapid Combo Test Cassette

CLEARED

Jan 31, 2022
451 days to decision

K203272 · Product code: **JHI** · Chemistry
Source: https://www.510kdatabase.net/k203272/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Nov 6, 2020
Decision date	Jan 31, 2022
Days to decision	451 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hangzhou AllTest Biotech Co., Ltd.**
Location	Hangzhou, CN
Contact	Rosa Wu
510(k) history	14 submissions · 14 cleared · 2019-2026

REGULATORY CONSULTANT

Consulting firm	**LSI International, Inc.**
Contact	Joe Shia

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