FDA 510(k) Premarket Notification

CLEARED

K182328 VeriClear Digital Early Result Pregnancy Test

May 15, 2019
261 days to decision

K182328 · Product code: **LCX** · Chemistry
Source: https://www.510kdatabase.net/k182328/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Aug 27, 2018
Decision date	May 15, 2019
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**True Diagnostics, Inc.**
Location	Carlsbad, CA, US
Contact	Jerry Lee
510(k) history	2 submissions · 2 cleared · 2017-2019

REGULATORY CONSULTANT

Consulting firm	**Axteria Biomed Consulting, Inc.**
Contact	Jinjie Hu

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k182328/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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