FDA 510(k) Premarket Notification

K200913 Clearblue® Early Digital Pregnancy Test

CLEARED

Aug 13, 2021
494 days to decision

K200913 · Product code: **LCX** · Chemistry
Source: https://www.510kdatabase.net/k200913/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Apr 6, 2020
Decision date	Aug 13, 2021
Days to decision	494 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Spd Swiss Precision Diagnostics GmbH**
Location	Geneva, CH
Contact	Joanne Scaife
510(k) history	4 submissions · 4 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	**Spd Development Company**
Contact	Kamila Przedmojska

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