

K213379 Clearblue® Early Pregnancy TestSep 21, 2022
343 days to decisionK213379 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k213379/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Oct 13, 2021
Decision date	Sep 21, 2022
Days to decision	343 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 Limited
Contact	Kamila Przedmojska

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

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