

**K210341 One Step Pregnancy Test**Mar 10, 2022  
398 days to decisionK210341 · Product code: **LCX** · Chemistry  
Source: <https://www.510kdatabase.net/k210341/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Feb 5, 2021
Decision date	Mar 10, 2022
Days to decision	398 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>SPD Development Company Limited</b>
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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