

**K252521 LifeStyles® HydraFeel Natural Rubber Latex Condom**Nov 18, 2025  
99 days to decisionK252521 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k252521/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Aug 11, 2025
Decision date	Nov 18, 2025
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Suretex Limited</b>
Location	Tambon Khao Kwai, Amphur Phunphin, TH
Contact	Nicolas Coltel
510(k) history	6 submissions · 6 cleared · 2022-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Digangi Consulting, LLC</b>
Contact	DiGangi Donna

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252521/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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