

**K232279 LifeStyles NRL Textured Condom**Oct 5, 2023  
66 days to decisionK232279 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k232279/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Jul 31, 2023
Decision date	Oct 5, 2023
Days to decision	66 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	Alison Arnot
510(k) history	6 submissions · 6 cleared · 2022-2025

**REGULATORY CONSULTANT**

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

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/k232279/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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