

K213921 Microthin Natural Rubber Latex CondomApr 28, 2022
134 days to decisionK213921 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k213921/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Dec 15, 2021
Decision date	Apr 28, 2022
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Suretex Limited
Location	Tambon Khao Kwai, Amphur Phunphin, TH
Contact	KC Nguyen
510(k) history	6 submissions · 6 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	C3-Carey Consultants, LLC
Contact	Carole C. Carey

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

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