

K181844 One TouchApr 15, 2019
278 days to decisionK181844 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k181844/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Jul 11, 2018
Decision date	Apr 15, 2019
Days to decision	278 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Thai Nippon Rubber Industry Public Company, Ltd.
Location	Bangkok, TH
Contact	Pisut Chanwatarungkull
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Kups International
Contact	Prabhat Garg

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181844/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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