

K210294 One Touch Spiral CondomSep 23, 2021
233 days to decisionK210294 · Product code: **HIS** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k210294/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Feb 2, 2021
Decision date	Sep 23, 2021
Days to decision	233 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Thai Nippon Rubber Industry Public Company Limited.
Location	Bangkok, TH
Contact	Ryosuke Takamiya
510(k) history	5 submissions · 5 cleared · 2018-2022

REGULATORY CONSULTANT

Consulting firm	Regulatory Insight, Inc.
Contact	Kevin Walls

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/k210294/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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