

K171213 One Touch Condom with BenzocaineJan 12, 2018
262 days to decisionK171213 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k171213/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Condom (HIS) |
| Date received | Apr 25, 2017 |
| Decision date | Jan 12, 2018 |
| Days to decision | 262 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k171213/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026