

K222068 Durex Penck III RegularOct 12, 2022
90 days to decisionK222068 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k222068/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Jul 14, 2022
Decision date	Oct 12, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rb Health (Us), LLC
Location	Parsippany, NJ, US
Contact	Kyle Prince
510(k) history	14 submissions · 14 cleared · 2019-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222068/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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