

K213647 Durex Patronus WideFeb 17, 2022
90 days to decisionK213647 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k213647/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Nov 19, 2021
Decision date	Feb 17, 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	Kaitlyn Chan
510(k) history	14 submissions · 14 cleared · 2019-2025

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