

K220489 Durex Patronus CloseFit, Durex Patronus RegularNov 7, 2022
258 days to decisionK220489 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k220489/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Feb 22, 2022
Decision date	Nov 7, 2022
Days to decision	258 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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