

K253642 Jada System (Jada-2002)May 15, 2026
177 days to decisionK253642 · Product code: **OQY** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k253642/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intrauterine Tamponade Balloon (OQY)
Date received	Nov 19, 2025
Decision date	May 15, 2026
Days to decision	177 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Organon, LLC
Location	Jersey City, NJ, US
Contact	Riddhish Patel
510(k) history	1 submissions · 1 cleared · 2026-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253642/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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