

K212757 Jada SystemSep 30, 2021
30 days to decisionK212757 · Product code: **OQY** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k212757/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intrauterine Tamponade Balloon (OQY)
Date received	Aug 31, 2021
Decision date	Sep 30, 2021
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Alydia Health
Location	Menlo Park, CA, US
Contact	Colby Holtshouse
510(k) history	2 submissions · 2 cleared · 2020-2021

REGULATORY CONSULTANT

Consulting firm	Domecus Consulting Services, LLC
Contact	Cindy Domecus

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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