

K223098 Bakri Essential Postpartum BalloonOct 28, 2022
28 days to decisionK223098 · Product code: **OQY** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k223098/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intrauterine Tamponade Balloon (OQY)
Date received	Sep 30, 2022
Decision date	Oct 28, 2022
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cook Incorporated
Location	Bloomington, IN, US
Contact	Ian Herman
510(k) history	175 submissions · 153 cleared · 2006-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223098/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026