

**K170622 Bakri Postpartum Balloon, Bakri Postpartum Balloon  
with Rapid Instillation Component**Mar 31, 2017  
30 days to decisionK170622 · Product code: **OQY** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k170622/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intrauterine Tamponade Balloon (OQY)
Date received	Mar 1, 2017
Decision date	Mar 31, 2017
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cook Incorporated</b>
Location	Bloomington, IN, US
Contact	Naomi Funkhouser
510(k) history	175 submissions · 153 cleared · 2006-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170622/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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