

**K230849 ELLAVI UBT**Nov 13, 2023  
230 days to decisionK230849 · Product code: **OQY** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k230849/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intrauterine Tamponade Balloon (OQY)
Date received	Mar 28, 2023
Decision date	Nov 13, 2023
Days to decision	230 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sinapi Biomedical (Pty) , Ltd.</b>
Location	Stellenbosch, ZA
Contact	Chris de Villiers
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Smith Associates</b>
Contact	Yolanda R Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230849/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026