FDA 510(k) Premarket Notification

K230849 ELLAVI UBT

CLEARED

Nov 13, 2023
230 days to decision

K230849 · Product code: **OQY** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k230849/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Smith Associates**
Contact	Yolanda R Smith

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