

K233043 Smart Scope® CXJun 14, 2024
263 days to decisionK233043 · Product code: **HEX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k233043/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colposcope (and Colpomicroscope) (HEX)
Date received	Sep 25, 2023
Decision date	Jun 14, 2024
Days to decision	263 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Periwinkle Technologies Pvt., Ltd.
Location	Pune, IN
Contact	Veena Muktali
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	IZiel Healthcare
Contact	Ankur Naik

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.netDevice record: <https://www.510kdatabase.net/k233043/> 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