

K193517 ViziShot 2 FLEXMar 18, 2020
90 days to decisionK193517 · Product code: **KTI** · Anesthesiology
Source: <https://www.510kdatabase.net/k193517/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope Accessory (KTI)
Date received	Dec 19, 2019
Decision date	Mar 18, 2020
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Olympus Surgical Technologies America
Location	Southborough, MA, US
Contact	Mary Anne Patella
510(k) history	12 submissions · 12 cleared · 2012-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193517/> 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 26, 2026