

**K163469 ViziShot 2 FLEX**Apr 6, 2017  
115 days to decisionK163469 · Product code: **KTI** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k163469/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope Accessory (KTI)
Date received	Dec 12, 2016
Decision date	Apr 6, 2017
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163469/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026