

**K200369 OES Elite Ureteroscopes and Accessories**Aug 28, 2020  
196 days to decisionK200369 · Product code: **FGB** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k200369/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Feb 14, 2020
Decision date	Aug 28, 2020
Days to decision	196 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Olympus Winter &amp; Ibe GmbH</b>
Location	Melville, NY, US
Contact	Stefanie Weber
510(k) history	42 submissions · 42 cleared · 1997-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200369/> 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 14, 2026