

**K190744 ENDOEYE HD II (WA50040A, WA50042A, WA50050A, WA50052A)**Aug 29, 2019  
160 days to decisionK190744 · Product code: **HET** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k190744/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Laparoscope, Gynecologic (and Accessories) (HET)
Date received	Mar 22, 2019
Decision date	Aug 29, 2019
Days to decision	160 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	Jan-Oliver Upmeier
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/k190744/>; 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