

**K162882 KARL STORZ ICG Imaging System**Jan 26, 2017  
104 days to decisionK162882 · Product code: **OWN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k162882/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Confocal Optical Imaging (OWN)
Date received	Oct 14, 2016
Decision date	Jan 26, 2017
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>KARL STORZ Endoscopy-America, Inc.</b>
Location	Mchenry, IL, US
Contact	SUSIE S. CHEN
510(k) history	361 submissions · 361 cleared · 1980-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162882/> 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