

**K193026 Visera Elite II Video System Center, Visera Elite II Endoeye 3D**Apr 3, 2020  
156 days to decisionK193026 · Product code: **GCJ** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k193026/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Oct 30, 2019
Decision date	Apr 3, 2020
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Olympus Medical Systems Corp.</b>
Location	Hachiochi-Shi, JP
Contact	Toshiyuki Nakajima
Website	<a href="https://www.olympus-global.com">https://www.olympus-global.com</a>
510(k) history	102 submissions · 102 cleared · 2012-2026

Olympus Medical Systems Corp. is a global medical device manufacturer headquartered in Hachiochi-Shi, Japan. The company specializes in endoscopic imaging systems and therapeutic devices for minimally invasive procedures. Olympus has received FDA 510(k) clearances from total submissions since 2012. The company's regulatory portfolio is dominated by Gastroenterology & Urology devices, including endoscopes, hemostatic forceps, biopsy instruments, and sphincterotomes. The latest clearance in 2026 reflects continued active development and market engagement. Recent cleared dev...

**REGULATORY CONSULTANT**

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Consulting firm	<b>Olympus Corporation of the Americas</b>
Contact	Lisa M. Boyle

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k193026/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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