

**K172817 4K CAMERA HEAD OLYMPUS CH-S400-XZ-EB, 4K
AUTOCLAVABLE CAMERA HEAD OLYMPUS CH-S400-XZ-EA**Oct 17, 2017
29 days to decisionK172817 · Product code: FET · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k172817/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Video Imaging System/component, Gastroenterology-urology (FET)
Date received	Sep 18, 2017
Decision date	Oct 17, 2017
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Olympus Medical Systems Corp.
Location	Hachiochi-Shi, JP
Contact	Toshiyuki Nakajima
Website	https://www.olympus-global.com
510(k) history	101 submissions · 101 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...

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Device record: <https://www.510kdatabase.net/k172817/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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