

**K203128 EVIS EUS ENDOSCOPIC ULTRASOUND CENTER
OLYMPUS EU-ME2/EVIS EUS ENDOSCOPIC ULTRASOUND
CENTER OLYMPUS EU-ME2 PREMIER PLUS**Nov 9, 2020
21 days to decisionK203128 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k203128/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Oct 19, 2020
Decision date	Nov 9, 2020
Days to decision	21 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...