FDA 510(k) Premarket Notification

CLEARED

K250862 EVIS EXERA III BRONCHOVIDEOSCOPE (OLYMPUS BF-XP190)

Jun 23, 2025
94 days to decision

K250862 · Product code: **EOQ** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k250862/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope (flexible Or Rigid) (EOQ)
Date received	Mar 21, 2025
Decision date	Jun 23, 2025
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	EVIS EXERA III BRONCHOVIDEOSCOPE (OLYMPUS BF-P190); EVIS EXERA III BRONCHOVIDEOSCOPE (OLYMPUS BF-XT190); BRONCHOVIDEOSCOPE (OLYMPUS BF-H1100); BRONCHOVIDEOSCOPE (OLYMPUS BF-1TH1100)

APPLICANT

Company	**Olympus Medical Systems Corp.**
Location	Hachiochi-Shi, JP
Contact	Tamada Osamu
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...

REGULATORY CONSULTANT

Consulting firm	**Olympus Corporation of the Americas**
Contact	Teffany Hutto

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