FDA 510(k) Premarket Notification

CLEARED

K143153 EVIS EXERA II DUODENOVIDEOSCOPE OLYMPUS TJF TYPE Q180V

Jan 15, 2016
438 days to decision

K143153 · Product code: **FDT** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k143153/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Duodenoscope And Accessories, Flexible/rigid (FDT)
Date received	Nov 3, 2014
Decision date	Jan 15, 2016
Days to decision	438 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...