

K113120 CHF-Y0005Sep 25, 2012
340 days to decisionK113120 · Product code: **FBN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k113120/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Choledochoscope And Accessories, Flexible/rigid (FBN)
Date received	Oct 21, 2011
Decision date	Sep 25, 2012
Days to decision	340 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Olympus Medical Systems Corp.
Location	Hachiochi-Shi, JP
Contact	SHERI MUSGNUNG
Website	https://www.olympus-global.com
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...
