

**K134026 ENDOSCOPE POSITION MARKING
PROBE,ENDOSCOPE POSITION DETECTING UNIT**Mar 7, 2014
67 days to decisionK134026 · Product code: **PGU** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k134026/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spatial Imaging For Display Of Endoscope Position (PGU)
Date received	Dec 30, 2013
Decision date	Mar 7, 2014
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Olympus Medical Systems Corp.
Location	Hachiochi-Shi, JP
Contact	DAPHNEY GERMAIN-KOLAWOLE
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...