FDA 510(k) Premarket Notification

# K120357 ENDOSCOPE REPROCESSOR OER-MINI

**CLEARED**

Dec 20, 2012
318 days to decision

K120357 · Product code: **FEB** · General Hospital
Source: https://www.510kdatabase.net/k120357/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Accessories, Cleaning, For Endoscope (FEB) |
| Date received | Feb 6, 2012 |
| Decision date | Dec 20, 2012 |
| Days to decision | 318 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Olympus Medical Systems Corp.** |
| Location | Hachiochi-Shi, JP |
| Contact | LAURA STORMS-TYLER |
| 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...