

K122505 SINGLE USE PRELOADED SPHINCTEROTOME VApr 11, 2013
238 days to decisionK122505 · Product code: **KNS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k122505/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS) |
| Date received | Aug 16, 2012 |
| Decision date | Apr 11, 2013 |
| Days to decision | 238 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...
