FDA 510(k) Premarket Notification

# K933110 OLYMPUS GUIDE WIRE

**CLEARED**

Nov 4, 1993
132 days to decision

K933110 · Product code: **OCY** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k933110/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Endoscopic Guidewire, Gastroenterology-urology (OCY) |
| Date received | Jun 25, 1993 |
| Decision date | Nov 4, 1993 |
| Days to decision | 132 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Olympus Corp.** |
| Location | Mchenry, IL, US |
| Contact | BARRY E SANDS |
| Website | https://www.olympus-global.com |
| 510(k) history | 142 submissions · 140 cleared · 1978-1995 |

Olympus Corp. is a Japanese optics and imaging manufacturer founded in 1919. The company operates from McHenry, US, and holds approximately 70 percent of the global endoscope market. Olympus has received FDA 510(k) clearances from total submissions between 1978 and 1995. The company's cleared devices span gastroenterology, urology, obstetrics, gynecology, and chemistry specialties. This regulatory record reflects the company's historical focus on endoscopic surgical instruments and related technologies. Notable cleared device categories include resection electrodes, fiber...