

K843899 GRC-WT, GRC-WJan 28, 1985
117 days to decisionK843899 · Product code: **HKI** · Ophthalmic
Source: <https://www.510kdatabase.net/k843899/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Camera, Ophthalmic, Ac-powered (HKI) |
| Date received | Oct 3, 1984 |
| Decision date | Jan 28, 1985 |
| Days to decision | 117 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Olympus Corp. |
| Location | Mchenry, IL, US |
| Contact | WALTER J SEIDL |
| 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...
