

K051789 VISANTE OCTSep 30, 2005
91 days to decisionK051789 · Product code: **HLI** · Ophthalmic
Source: <https://www.510kdatabase.net/k051789/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ophthalmoscope, Ac-powered (HLI) |
| Date received | Jul 1, 2005 |
| Decision date | Sep 30, 2005 |
| Days to decision | 91 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Carl Zeiss Meditec, Inc. |
| Location | San Diego, CA, US |
| Contact | JUDITH A BRIMACOMBE |
| Website | https://www.zeiss.com/meditec |
| 510(k) history | 29 submissions · 29 cleared · 1993-2025 |

Carl Zeiss Meditec, Inc. is a global medical device manufacturer specializing in innovative solutions for ophthalmology and microsurgery. The company operates with a manufacturing facility in San Diego, California, and is part of the ZEISS Group, a leader in optical and optoelectronic technologies since 1846. The company maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions. Ophthalmic devices represent the dominant focus, accounting for approximately 86% of submissions. Carl Zeiss Meditec has been active in FDA clearances since...
