

K133217 CIRRUS PHOTOMar 19, 2014
152 days to decisionK133217 · Product code: **OBO** · Ophthalmic
Source: <https://www.510kdatabase.net/k133217/>**SUBMISSION DETAILS**

| | |
|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Tomography, Optical Coherence (OBO) |
| Date received | Oct 18, 2013 |
| Decision date | Mar 19, 2014 |
| Days to decision | 152 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Carl Zeiss Meditec, AG |
| Location | Dublin, CA, US |
| Contact | MANDY AMBRECHT |
| Website | http://www.zeiss.com/meditec-ag/en_de/home.html |
| 510(k) history | 45 submissions · 44 cleared · 2004-2025 |

Carl Zeiss Meditec, AG is a global medical device manufacturer specializing in innovative solutions for ophthalmology and microsurgery. The company operates with a manufacturing facility in Dublin, US, and delivers diagnostic and surgical instruments to healthcare professionals worldwide. The company has received FDA 510(k) clearances from total submissions since 2004. Ophthalmic devices represent the dominant category, accounting for 71% of submissions. The latest clearance in 2025 reflects continued regulatory activity and product innovation in this specialized field. C...
