

**K951132 ANGIOSCAN (AS STAND ALONE INSTRUMENT)**Jun 26, 1995  
105 days to decisionK951132 · Product code: **HLI** · Ophthalmic  
Source: <https://www.510kdatabase.net/k951132/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Ophthalmoscope, Ac-powered (HLI)   |
| Date received         | Mar 13, 1995                       |
| Decision date         | Jun 26, 1995                       |
| Days to decision      | 105 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Carl Zeiss Meditec, Inc.</b>   |
| Location       | San Diego, CA, US   |
| Contact        | ANDREAS W DREHER  |
| Website        | <a href="https://www.zeiss.com/meditec">https://www.zeiss.com/meditec</a> |
| 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...

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