

**K101182 IOLMASTER 500**Nov 3, 2010  
190 days to decisionK101182 · Product code: **HJO** · Ophthalmic  
Source: <https://www.510kdatabase.net/k101182/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)         |
| Submission type       | Traditional                                |
| Device classification | Biomicroscope, Slit-lamp, Ac-powered (HJO) |
| Date received         | Apr 27, 2010                               |
| Decision date         | Nov 3, 2010                                |
| Days to decision      | 190 days                                   |
| Third-party review    | No   |
| Summary / Statement   | Summary                                    |

**APPLICANT**

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|----------------|---|
| Company        | <b>Carl Zeiss Meditec, AG</b>   |
| Location       | Dublin, CA, US  |
| Contact        | JUDITH A BRIMACOMBE   |
| Website        | <a href="http://www.zeiss.com/meditec-ag/en_de/home.html">http://www.zeiss.com/meditec-ag/en_de/home.html</a> |
| 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...

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