FDA 510(k) Premarket Notification

# K103056 VISULAS TRION LASER SYSTEM WITH THE VITE OPTION

**CLEARED**

Feb 1, 2011
109 days to decision

K103056 · Product code: **HQF** · Ophthalmic
Source: https://www.510kdatabase.net/k103056/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Laser, Ophthalmic (HQF) |
| Date received | Oct 15, 2010 |
| Decision date | Feb 1, 2011 |
| Days to decision | 109 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Carl Zeiss Meditec, AG** |
| Location | Dublin, CA, US |
| Contact | JUDITH A BRIMACOMBE |
| 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...