

K162991 YELLOW 560 Fluorescence ModuleJul 24, 2017
270 days to decisionK162991 · Product code: **IZI** · Radiology
Source: <https://www.510kdatabase.net/k162991/>**SUBMISSION DETAILS**

| | |
|-----------------------|-----------------------------------|
| Decision | Substantially Equivalent - SD |
| Submission type | Traditional |
| Device classification | System, X-ray, Angiographic (IZI) |
| Date received | Oct 27, 2016 |
| Decision date | Jul 24, 2017 |
| Days to decision | 270 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Carl Zeiss Meditec, AG |
| Location | Dublin, CA, US |
| Contact | Peter Schrutka-Rechtenstamm |
| 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...

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