

**K230858 QUATERA 700**Jul 31, 2023  
124 days to decisionK230858 · Product code: **HQC** · Ophthalmic  
Source: <https://www.510kdatabase.net/k230858/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Phacofragmentation (HQC)
Date received	Mar 29, 2023
Decision date	Jul 31, 2023
Days to decision	124 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Carl Zeiss Meditec, AG</b>
Location	Dublin, CA, US
Contact	Hans-Joachim Miesner
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...

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Carl Zeiss Meditec, Inc.</b>
Contact	Aditya Rao

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k230858/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026