FDA 510(k) Premarket Notification

K100253 VISUMAX LASER KERATOME

CLEARED

Jul 8, 2010
161 days to decision

K100253 · Product code: **HQF** · Ophthalmic
Source: https://www.510kdatabase.net/k100253/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Ophthalmic (HQF)
Date received	Jan 28, 2010
Decision date	Jul 8, 2010
Days to decision	161 days
Third-party review	Yes
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...