FDA 510(k) Premarket Notification

K042139 VISULAS YAG III

CLEARED

Sep 9, 2004
31 days to decision

K042139 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k042139/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 9, 2004
Decision date	Sep 9, 2004
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Carl Zeiss Meditec, AG**
Location	Dublin, CA, US
Contact	R. MICHAEL CROMPTON
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...