FDA 510(k) Premarket Notification

CLEARED

K100035 MODEL VISULAS 532S LASER WITH THE VITE OPTION

Mar 17, 2010
70 days to decision

K100035 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k100035/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 6, 2010
Decision date	Mar 17, 2010
Days to decision	70 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...