

K072514 VISULAS TRIONSep 21, 2007
14 days to decisionK072514 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k072514/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 7, 2007
Decision date	Sep 21, 2007
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Carl Zeiss Meditec, AG
Location	Dublin, CA, US
Contact	KENT W JONES
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...
