FDA 510(k) Premarket Notification

K232051 VISULAS green

CLEARED

Oct 24, 2023
106 days to decision

K232051 · Product code: **HQF** · Ophthalmic
Source: https://www.510kdatabase.net/k232051/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Ophthalmic (HQF)
Date received	Jul 10, 2023
Decision date	Oct 24, 2023
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Carl Zeiss Meditec**
Location	Dublic, CA, US
Contact	Tanesha Bland
Website	http://www.zeiss.com/meditec-ag/en_de/home.html
510(k) history	1 submissions · 1 cleared · 2023-2023

Carl Zeiss Meditec is a global medical technology company specializing in ophthalmic solutions. The company develops diagnostic and surgical instruments for eye care professionals worldwide, with a manufacturing facility in Dublin, US. Carl Zeiss Meditec has received FDA 510(k) clearance from total submission. The company's regulatory activity is focused entirely on ophthalmic devices. The most recent clearance dates to 2023, representing the company's historical FDA record. The company's cleared device portfolio includes the VISULAS green system, a laser-based ophthalmic...