FDA 510(k) Premarket Notification

K173371 VisuMax Femtosecond Laser

CLEARED

Apr 13, 2018
168 days to decision

K173371 · Product code: **HNO** · Ophthalmic
Source: https://www.510kdatabase.net/k173371/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Keratome, Ac-powered (HNO)
Date received	Oct 27, 2017
Decision date	Apr 13, 2018
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Carl Zeiss Meditec, Inc.**
Location	San Diego, CA, US
Contact	Todd Otani
510(k) history	29 submissions · 29 cleared · 1993-2025