FDA 510(k) Premarket Notification

K213559 FEMTO LDV Z8 Femtosecond Surgical Laser

CLEARED

Apr 21, 2022
168 days to decision

K213559 · Product code: **OOE** · Ophthalmic
Source: https://www.510kdatabase.net/k213559/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmic Femtosecond Laser (OOE)
Date received	Nov 4, 2021
Decision date	Apr 21, 2022
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sie Ag,Surgical Instrument Engineering**
Location	Port, CH
Contact	Frank Ziemer
510(k) history	2 submissions · 2 cleared · 2015-2022

REGULATORY CONSULTANT

Consulting firm	**Regulatory Insight, Inc.**
Contact	Kevin Walls

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov