FDA 510(k) Premarket Notification

K131207 FEMTO LDV(TM) Z-GENERATION FEMTOSECOND SURGICAL LASER

CLEARED

Oct 9, 2013
163 days to decision

K131207 · Product code: **HQF** · Ophthalmic
Source: https://www.510kdatabase.net/k131207/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Ophthalmic (HQF)
Date received	Apr 29, 2013
Decision date	Oct 9, 2013
Days to decision	163 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Surgical Instrument Engineering AG**
Location	Littleton, CO, US
Contact	Kevin Walls
510(k) history	1 submissions · 1 cleared · 2013-2013