

K131207 FEMTO LDV(TM) Z-GENERATION FEMTOSECOND SURGICAL LASEROct 9, 2013
163 days to decisionK131207 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131207/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 8, 2026