

K123859 TBDMar 27, 2013
103 days to decisionK123859 · Product code: **OOE** · Ophthalmic
Source: <https://www.510kdatabase.net/k123859/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmic Femtosecond Laser (OOE)
Date received	Dec 14, 2012
Decision date	Mar 27, 2013
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Lensar, Inc.
Location	Winter Park, FL, US
Contact	SHIRLEY K MCGARVEY
510(k) history	14 submissions · 14 cleared · 2010-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123859/> 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 May 27, 2026