FDA 510(k) Premarket Notification

K123859 TBD

CLEARED

Mar 27, 2013
103 days to decision

K123859 · 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