FDA 510(k) Premarket Notification

K092647 LENSX 550 LASER SYSTEM

CLEARED

Dec 11, 2009
106 days to decision

K092647 · Product code: **OOE** · Ophthalmic
Source: https://www.510kdatabase.net/k092647/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmic Femtosecond Laser (OOE)
Date received	Aug 27, 2009
Decision date	Dec 11, 2009
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lensx Lasers, Inc.**
Location	Laguna Beach, CA, US
Contact	Judy Gordon
510(k) history	4 submissions · 4 cleared · 2009-2010