FDA 510(k) Premarket Notification

K094052 LENSX 550 LASER SYSTEM. MODEL 550

CLEARED

Apr 23, 2010
113 days to decision

K094052 · Product code: **OOE** · Ophthalmic
Source: https://www.510kdatabase.net/k094052/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmic Femtosecond Laser (OOE)
Date received	Dec 31, 2009
Decision date	Apr 23, 2010
Days to decision	113 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