FDA 510(k) Premarket Notification

K243896 LenSx Laser System (8065998162)

CLEARED

Apr 28, 2025
131 days to decision

K243896 · Product code: **OOE** · Ophthalmic
Source: https://www.510kdatabase.net/k243896/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmic Femtosecond Laser (OOE)
Date received	Dec 18, 2024
Decision date	Apr 28, 2025
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Alcon Laboratories, Inc.**
Location	Fort Worth, TX, US
Contact	Tammy Vu
Website	https://www.alcon.com
510(k) history	43 submissions · 42 cleared · 1996-2026

Alcon Laboratories, Inc. is an eye care company headquartered in Fort Worth, Texas. The company develops innovative vision products and treatments for patients worldwide. Alcon maintains a strong FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions. The company specializes exclusively in Ophthalmic devices, a focus reflected across its entire submission portfolio. Alcon's regulatory activity spans from 1996 to 2026, with recent clearances demonstrating continued innovation in vision care technologies. Recent FDA 510(k) clearances include con...