

**K161288 LenSX Laser System**Nov 16, 2016  
191 days to decisionK161288 · Product code: **OOE** · Ophthalmic  
Source: <https://www.510kdatabase.net/k161288/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmic Femtosecond Laser (OOE)
Date received	May 9, 2016
Decision date	Nov 16, 2016
Days to decision	191 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Alcon Laboratories, Inc.</b>
Location	Fort Worth, TX, US
Contact	JAMES ARGANDA
Website	<a href="https://www.alcon.com">https://www.alcon.com</a>
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...

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