FDA 510(k) Premarket Notification

# K000637 CUSTOMCORNEA MEASUREMENT DEVICE (CCMD)

**CLEARED**

May 19, 2000
84 days to decision

K000637 · Product code: **NCF** · Ophthalmic
Source: https://www.510kdatabase.net/k000637/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent - U |
| Submission type | Traditional |
| Device classification | Aberrometer, Ophthalmic (NCF) |
| Date received | Feb 25, 2000 |
| Decision date | May 19, 2000 |
| Days to decision | 84 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **Alcon Laboratories, Inc.** |
| Location | Fort Worth, TX, US |
| Contact | S.K. MCGARVEY |
| 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...