

K212039 CLAREON MONARCH IV IOL Delivery SystemAug 23, 2021
54 days to decisionK212039 · Product code: **MSS** · Ophthalmic
Source: <https://www.510kdatabase.net/k212039/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Folders And Injectors, Intraocular Lens (iol) (MSS)
Date received	Jun 30, 2021
Decision date	Aug 23, 2021
Days to decision	54 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	Jwalitha Shankardas
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...