

K233876 UNITY VCS (8065000296)Jun 21, 2024
197 days to decisionK233876 · Product code: **HQC** · Ophthalmic
Source: <https://www.510kdatabase.net/k233876/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Phacofragmentation (HQC)
Date received	Dec 7, 2023
Decision date	Jun 21, 2024
Days to decision	197 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	UNITY CS (8065000297)

APPLICANT

Company	Alcon Laboratories, Inc.
Location	Fort Worth, TX, US
Contact	Ganesh Balachandar
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...