FDA 510(k) Premarket Notification

CLEARED

K172314 Ampleye Scleral RGP Lens (roflufocon D, roflufocon E, hexafocon A, paflufocon D)

Sep 20, 2017
50 days to decision

K172314 · Product code: **HQD** · Ophthalmic
Source: https://www.510kdatabase.net/k172314/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lens, Contact (other Material) - Daily (HQD)
Date received	Aug 1, 2017
Decision date	Sep 20, 2017
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Art Optical Contact Lens, Inc.**
Location	Grand Junction, CO, US
Contact	Mike Johnson
510(k) history	6 submissions · 6 cleared · 2008-2023