FDA 510(k) Premarket Notification

CLEARED

K213880 Custom Stable Rigid Gas Permeable Scleral Contact Lens

Jan 7, 2022
25 days to decision

K213880 · Product code: **HQD** · Ophthalmic
Source: https://www.510kdatabase.net/k213880/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lens, Contact (other Material) - Daily (HQD)
Date received	Dec 13, 2021
Decision date	Jan 7, 2022
Days to decision	25 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Valley Contax, Inc.**
Location	Springfield, OR, US
Contact	Josh Adams
510(k) history	3 submissions · 3 cleared · 2017-2022

REGULATORY CONSULTANT

Consulting firm	**Eyereg Consulting, Inc.**
Contact	Bret Andre

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov