FDA 510(k) Premarket Notification

CLEARED

K221517 POLYVUE (polymacon) Soft (hydrophilic) Contact Lens, POLYVUE COLOR (polymacon) Soft (hydrophilic) Contact Lens

Oct 4, 2022
132 days to decision

K221517 · Product code: **LPL** · Ophthalmic
Source: https://www.510kdatabase.net/k221517/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	May 25, 2022
Decision date	Oct 4, 2022
Days to decision	132 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**INTEROJO, Inc.**
Location	Seoul, KR
Contact	Si-Chul Rho
510(k) history	3 submissions · 3 cleared · 2015-2022

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