

K220045 TREVUES (polymacon) Soft (hydrophilic) Contact Lenses (Tinted, Color)Aug 5, 2022
212 days to decisionK220045 · Product code: LPL · Ophthalmic
Source: <https://www.510kdatabase.net/k220045/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Jan 5, 2022
Decision date	Aug 5, 2022
Days to decision	212 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dk Medivision Co., Ltd.
Location	Chungcheongnam-Do, KR
Contact	Henry Hong
510(k) history	1 submissions · 1 cleared · 2022-2022

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220045/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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