FDA 510(k) Premarket Notification

K220143 BARBIE (polymacon) Daily Wear Soft (Hydrophilic) Contact Lens

CLEARED

Sep 8, 2022
233 days to decision

K220143 · Product code: **LPL** · Ophthalmic
Source: https://www.510kdatabase.net/k220143/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Jan 18, 2022
Decision date	Sep 8, 2022
Days to decision	233 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Dashicheng Optical Technology Co., Ltd.**
Location	Shenzhen, CN
Contact	Jiayi Li
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Shenzhen Joyantech Consulting Co., Ltd.**
Contact	Grace Liu

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