FDA 510(k) Premarket Notification

CLEARED

Nov 13, 2018
48 days to decision

K182674 Largan U38 (Polymacon) Daily Wear Soft (hydrophilic) Contact Lens, Largan U38 (Polymacon) Daily Wear Soft (hydrophilic) Contact Lens for Astigmatism, Largan U38 (Polymacon) Daily Wear Soft (hydrophilic) Contact Lens for Presbyopia

K182674 · Product code: **LPL** · Ophthalmic
Source: https://www.510kdatabase.net/k182674/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Sep 26, 2018
Decision date	Nov 13, 2018
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Largan Medical Co., Ltd.**
Location	Taichung, TW
Contact	Amy Tien
510(k) history	8 submissions · 8 cleared · 2017-2025