FDA 510(k) Premarket Notification

CLEARED

K171157 PolyDev Soft Contact Lenses

Jun 2, 2017
43 days to decision

K171157 · Product code: **LPL** · Ophthalmic
Source: https://www.510kdatabase.net/k171157/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Apr 20, 2017
Decision date	Jun 2, 2017
Days to decision	43 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Polydev , Ltd.**
Location	Collon, IE
Contact	John Mulvihill
510(k) history	3 submissions · 3 cleared · 2016-2017

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k171157/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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