

K153305 EyeYon (hioxirilcon D) Soft (hydrophillc) ContactLensesfor Daily Wear, Hyper-CL (hioxirilcon D)TherapeuticSoft (hydrophillc) Contact Lensesfor Daily Wear

Apr 8, 2016
144 days to decision

K153305 · Product code: LPL · Ophthalmic
Source: <https://www.510kdatabase.net/k153305/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Nov 16, 2015
Decision date	Apr 8, 2016
Days to decision	144 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Eyeyon Medical
Location	Nes Ziona, IL
Contact	MALCA CHEN-ZION
510(k) history	1 submissions · 1 cleared · 2016-2016

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k153305/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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