FDA 510(k) Premarket Notification

K201013 Optixon 1-Day

CLEARED

Sep 18, 2020
154 days to decision

K201013 · Product code: **LPL** · Ophthalmic
Source: https://www.510kdatabase.net/k201013/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Apr 17, 2020
Decision date	Sep 18, 2020
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Optixon, Inc.**
Location	Daegu, KR
Contact	Oh Jeong Ju
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Igc Co., Ltd.**
Contact	Eunbae Cho

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