

K201013 Optixon 1-DaySep 18, 2020
154 days to decisionK201013 · Product code: **LPL** · Ophthalmic
Source: <https://www.510kdatabase.net/k201013/>**SUBMISSION DETAILS**

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|-----------------------|--|
| 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](https://accessdata.fda.gov)

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