FDA 510(k) Premarket Notification

# K183175 BostonSight Scleral

**CLEARED**

Jan 4, 2019
49 days to decision

K183175 · Product code: **HQD** · Ophthalmic
Source: https://www.510kdatabase.net/k183175/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Lens, Contact (other Material) - Daily (HQD) |
| Date received | Nov 16, 2018 |
| Decision date | Jan 4, 2019 |
| Days to decision | 49 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Bostonsight** |
| Location | Needham, MA, US |
| Contact | Gene Guselli |
| 510(k) history | 2 submissions · 2 cleared · 2016-2019 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Eyereg Consulting, Inc.** |
| Contact | Bret Andre |

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