

K183175 BostonSight ScleralJan 4, 2019
49 days to decisionK183175 · Product code: **HQD** · Ophthalmic
Source: <https://www.510kdatabase.net/k183175/>**SUBMISSION DETAILS**

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

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