

**K182986 Boston Keratoprosthesis, Type I Lucia**Jan 30, 2019  
93 days to decisionK182986 · Product code: **HQM** · Ophthalmic  
Source: <https://www.510kdatabase.net/k182986/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Keratoprosthesis, Permanent Implant (HQM)
Date received	Oct 29, 2018
Decision date	Jan 30, 2019
Days to decision	93 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Massachusetts Eye and Ear Infirmary D/B/A Boston</b>
Location	Boston, MA, US
Contact	James Chodosh
510(k) history	1 submissions · 1 cleared · 2019-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Namsa</b>
Contact	Kristy Katzenmeyer-Pleuss

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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