FDA 510(k) Premarket Notification

K182986 Boston Keratoprosthesis, Type I Lucia

CLEARED

Jan 30, 2019
93 days to decision

K182986 · Product code: **HQM** · Ophthalmic
Source: https://www.510kdatabase.net/k182986/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Namsa**
Contact	Kristy Katzenmeyer-Pleuss

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