

K200667 EyeArtAug 3, 2020
143 days to decisionK200667 · Product code: **PIB** · Ophthalmic
Source: <https://www.510kdatabase.net/k200667/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diabetic Retinopathy Detection Device (PIB)
Date received	Mar 13, 2020
Decision date	Aug 3, 2020
Days to decision	143 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Eyenuk, Inc.
Location	Los Angeles, CA, US
Contact	Kaushal Solanki
510(k) history	2 submissions · 2 cleared · 2020-2023

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