

K253704 iPredict-DR

Jul 2, 2026
220 days to decision

K253704 · Product code: **PIB** · Ophthalmic
Source: <https://www.510kdatabase.net/k253704/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diabetic Retinopathy Detection Device (PIB)
Date received	Nov 24, 2025
Decision date	Jul 2, 2026
Days to decision	220 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	iHealthscreen, Inc.
Location	Richmond Hill, NY, US
Contact	Alauddin Bhuiyan
510(k) history	1 submissions · 1 cleared · 2026-2026