

K193319 XyCAM RI, XyCAM RI System, XyCAM Retinal Imaging SystemJun 1, 2020
182 days to decisionK193319 · Product code: **HKI** · Ophthalmic
Source: <https://www.510kdatabase.net/k193319/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Dec 2, 2019
Decision date	Jun 1, 2020
Days to decision	182 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vasoptic Medical, Inc.
Location	Baltimore, MD, US
Contact	Abhishek Rege
510(k) history	1 submissions · 1 cleared · 2020-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193319/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026