

K202097 Fundus CameraFeb 2, 2021
188 days to decisionK202097 · Product code: **HKI** · Ophthalmic
Source: <https://www.510kdatabase.net/k202097/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Jul 29, 2020
Decision date	Feb 2, 2021
Days to decision	188 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Huvitz Co., Ltd.
Location	Flintville, TN, US
Contact	Hyung Min Heo
510(k) history	6 submissions · 6 cleared · 2008-2023

REGULATORY CONSULTANT

Consulting firm	Mtechgroup
Contact	Dave Kim

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202097/> 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 May 25, 2026