FDA 510(k) Premarket Notification

K202097 Fundus Camera

CLEARED

Feb 2, 2021
188 days to decision

K202097 · 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