FDA 510(k) Premarket Notification

K232143 Applanation Tonometer HT-5000

CLEARED

Oct 23, 2023
96 days to decision

K232143 · Product code: **HKY** · Ophthalmic
Source: https://www.510kdatabase.net/k232143/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tonometer, Manual (HKY)
Date received	Jul 19, 2023
Decision date	Oct 23, 2023
Days to decision	96 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Huvitz Co., Ltd.**
Location	Flintville, TN, US
Contact	Heo Hyung-Min
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