

**K232143 Applanation Tonometer HT-5000**Oct 23, 2023  
96 days to decisionK232143 · Product code: **HKY** · Ophthalmic  
Source: <https://www.510kdatabase.net/k232143/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mtechgroup</b>
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.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232143/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026