

K181260 MiiS Horus Scope DPT 100Jun 21, 2019
406 days to decisionK181260 · Product code: **HKX** · Ophthalmic
Source: <https://www.510kdatabase.net/k181260/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tonometer, Ac-powered (HKX)
Date received	May 11, 2018
Decision date	Jun 21, 2019
Days to decision	406 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medimaging Integrated Solution, Inc (Miis)
Location	Hsinchu, TW
Contact	Chih-Lu Hsu
510(k) history	7 submissions · 7 cleared · 2017-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181260/> 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