

**K211355 iCare HOME2**Jan 25, 2022  
267 days to decisionK211355 · Product code: **HKY** · Ophthalmic  
Source: <https://www.510kdatabase.net/k211355/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tonometer, Manual (HKY)
Date received	May 3, 2021
Decision date	Jan 25, 2022
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Icare Finland OY</b>
Location	Vantaa, FI
Contact	Hannes Hyvönen
510(k) history	7 submissions · 7 cleared · 2016-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211355/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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