

K220852 iCare IC200Oct 6, 2022
197 days to decisionK220852 · Product code: **HKY** · Ophthalmic
Source: <https://www.510kdatabase.net/k220852/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tonometer, Manual (HKY)
Date received	Mar 23, 2022
Decision date	Oct 6, 2022
Days to decision	197 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220852/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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