

K153694 Icare ic100Apr 19, 2016
118 days to decisionK153694 · Product code: **HKY** · Ophthalmic
Source: <https://www.510kdatabase.net/k153694/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tonometer, Manual (HKY)
Date received	Dec 23, 2015
Decision date	Apr 19, 2016
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153694/> 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 26, 2026