

**K241447 iCare ST500 (TA04)**Sep 27, 2024  
128 days to decisionK241447 · Product code: **HKY** · Ophthalmic  
Source: <https://www.510kdatabase.net/k241447/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tonometer, Manual (HKY)
Date received	May 22, 2024
Decision date	Sep 27, 2024
Days to decision	128 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

**CLINICAL EVIDENCE - NCT05742009****iCare ST500 Clinical Trial**

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Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	165 patients (actual)
Study sites	1 site
Condition studied	Intraocular Pressure
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Nov 14, 2023
Sponsor	Icare Finland Oy (Industry)

**Primary outcome**

Demonstrate compliance with ANSI Z80.10:2014-Ophthalmics-Ophthalmic Instruments-Tonometers

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT05742009](https://clinicaltrials.gov/study/NCT05742009)