

**K253039 AUTO KERATO-REFRACTO TONOMETER TRK-3  
OMNIA**Nov 7, 2025  
46 days to decisionK253039 · Product code: **HKX** · Ophthalmic  
Source: <https://www.510kdatabase.net/k253039/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tonometer, Ac-powered (HKX)
Date received	Sep 22, 2025
Decision date	Nov 7, 2025
Days to decision	46 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Topcon Corporation</b>
Location	North Reading, MA, US
Contact	Tomoka Nishiyama
Website	<a href="http://www.topcon.com">http://www.topcon.com</a>
510(k) history	13 submissions · 13 cleared · 2014-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Orasi Consulting, LLC</b>
Contact	Lena Sattler

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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