

K220090 Visibly Digital Acuity ProductAug 12, 2022
213 days to decisionK220090 · Product code: **QTO** · Ophthalmic
Source: <https://www.510kdatabase.net/k220090/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Digital Visual Acuity Test (QTO)
Date received	Jan 11, 2022
Decision date	Aug 12, 2022
Days to decision	213 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Visibly, Inc.
Location	Chicago, IL, US
Contact	Paul Foley
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Janice M. Hogan

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

CLINICAL EVIDENCE - NCT05026658**Prospective, Randomized, Controlled Agreement and Reproducibility Clinical Study**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	358 patients (actual)
Study sites	3 sites
Condition studied	Digital Acuity Product
Primary purpose	Other
Study type	Interventional
Study design	Parallel
Masking	Open label
Completion date	Oct 4, 2021
Sponsor	Visibly (Industry)

Primary outcome

Effectiveness

Secondary outcome

Effectiveness

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05026658