FDA 510(k) Premarket Notification

K231673 P200TE (A10700)

CLEARED

Aug 18, 2023
71 days to decision

K231673 · Product code: **OBO** · Ophthalmic
Source: https://www.510kdatabase.net/k231673/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Jun 8, 2023
Decision date	Aug 18, 2023
Days to decision	71 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Optos Plc.**
Location	Washington, DC, US
Contact	Rachel Reay
Website	http://www.optos.com/
510(k) history	15 submissions · 15 cleared · 1999-2024

Optos Plc. is a leading developer of ultra-widefield retinal imaging systems for eyecare professionals. The company specializes in innovative diagnostic devices that capture panoramic retinal images in a single shot. Now part of Nikon Corporation, Optos continues to operate as a distinct brand with a manufacturing facility in Washington, US. Optos has an established FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions. All submissions focus on Ophthalmic devices. The company's first clearance was in 1999, with the most recent clearance in 2024, d...

CLINICAL EVIDENCE - NCT05624593

P200TE and Predicate Agreement and Precision Study

Status	Unknown - *No results published to ClinicalTrials.gov*
Enrollment	125 patients (estimated)
Study sites	1 site
Condition studied	Normal; Retina Disease; Glaucoma
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Mar 1, 2023
Sponsor	Optos, PLC (Industry)

Primary outcome

Limit of Agreement (LOA) between the P200TE and predicate device measurements of full retinal thickness.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05624593