K221320 Scanning Laser Ophthalmoscope Mirante [SLO/OCT Model] with Image Filing Software NAVIS-EX

CLEARED

Mar 30, 2023
328 days to decision

K221320 · Product code: **OBO** · Ophthalmic
Source: https://www.510kdatabase.net/k221320/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	May 6, 2022
Decision date	Mar 30, 2023
Days to decision	328 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Scanning Laser Ophthalmoscope Mirante [SLO Model] with Image Filing Software NAVIS-EX

APPLICANT

Company	**Nidek Co., Ltd.**
Location	Lake Forest, CA, US
Contact	Tsutomu Sunada
510(k) history	20 submissions · 19 cleared · 2001-2023

REGULATORY CONSULTANT

Consulting firm	**Ora, Inc.**
Contact	Ryan Bouchard

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

CLINICAL EVIDENCE - NCT04318132

Agreement and Precision Study of the Nidek Mirante

Status	Completed
Enrollment	170 patients (actual)
Study sites	1 site
Condition studied	Glaucoma; Retinal Disease; Corneal Disease
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Dec 30, 2021
Sponsor	Nidek Co. LTD. (Industry)

Primary outcome

Agreement of Macular Thickness (?m) Measurement for Nidek Mirante and Optovue RTVue XR Avanti OCT

Secondary outcome

Adverse Events

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04318132