March 30, 2023

Nidek Co., LTD.
% Ryan Bouchard
Official Correspondent
Ora, Inc.
300 Brickstone Square
Andover, Massachusetts 01810

Re: K221320
Trade/Device Name:
Scanning Laser Ophthalmoscope Mirante [SLO/OCT Model] with Image Filing Software NAVIS-EX
Scanning Laser Ophthalmoscope Mirante [SLO Model] with Image Filing Software NAVIS-EX
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO, MYC, NFJ
Dated: February 22, 2023
Received: February 24, 2023

Dear Ryan Bouchard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elvin Y. Ng -S

Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221320

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

Indications for Use *(Describe)*

Scanning Laser Ophthalmoscope Mirante [SLO/OCT Model]

The Mirante SLO/OCT with scanning laser ophthalmoscope and optical coherence tomography function and with Image Filing Software NAVIS-EX is a non-contact system for imaging the fundus and for axial cross sectional imaging of ocular structures. It is indicated for in vivo imaging and measurement of:

• the retina, retinal nerve fiber layer, optic disc, and
• the anterior chamber and cornea (when used with the optional anterior segment OCT adapter)

and for color, angiography, autofluorescence, and retro mode imaging of the retina as an aid in the diagnosis and management. The Image Filing Software NAVIS-EX is a software system intended for use to store, manage, process, measure, analyze and display patient data and clinical information from computerized diagnostic instruments through networks. It is intended to work with compatible NIDEK ophthalmic devices.

Scanning Laser Ophthalmoscope Mirante [SLO Model]

The Mirante SLO with scanning laser ophthalmoscope function and with Image Filing Software NAVIS-EX is a non-contact system for imaging the fundus. It is indicated for color, angiography, auto-fluorescence, and retro mode imaging of the retina as an aid in the diagnosis and management. The Image Filing Software NAVIS-EX is a software system intended for use to store, manage, process, measure, analyze and display patient data and clinical information from computerized diagnostic instruments through networks. It is intended to work with compatible NIDEK ophthalmic devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k)

Summary

K221320

This summary of the 510(k) premarket notification for the Nidek Mirante with NAVIS-EX Software is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Owner Company name, address

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Contact/Application Correspondent

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Date Prepared

March 30, 2023

Name of Device - Mirante

Trade Name:

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

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

Common Name:	Optical Coherence Tomography
Classification Name:	Ophthalmoscope
Classification Regulation:	21 CFR 886.1570
Product Code:	OBO, MYC, NFJ

Predicate Devices

Primary predicate:	Avanti (K180660)
Secondary predicate:	P200DTx: (K142897)
	Image Filing Software NAVIS-EX: (K181345)

OCT/SLO Device Description

The Nidek Mirante is an Optical Coherence Tomography (OCT) system intended for use as a non-invasive imaging device for viewing and measuring ocular tissue structures with micrometer range resolution. The Nidek Mirante is a computer controlled ophthalmic imaging system. The device scans the patient's eye using a low coherence interferometer to measure the reflectivity of retinal tissue. The cross sectional retinal tissue structure is composed of a sequence of A-scans. It has a traditional patient and instrument interface like most ophthalmic devices.

The Nidek Mirante uses Fourier Domain OCT, a method that involves spectral analysis of the returned light rather than mechanic moving parts in the depth scan. Fourier Domain OCT allows scan speeds about 65 times faster than the mechanical limited Time Domain scan speeds.

The Mirante utilizes Fourier spectroscopic imaging using a Michelson interferometer. The interfering light of the reference light and the reflected light from the test eye obtained by the Michelson interferometer are spectrally divided by a diffraction grating and the signal is acquired by a line scan camera. The signal is inverse Fourier transformed to obtain the reflection intensity distribution in the depth direction of the patient's eye. The galvano mirror scans the imaging light in the XY direction to obtain a tomographic image.

The OCT scan patterns include the following:

Retinal Scan Patterns

- Macula Line
- Macula Cross
- Macula Map
- Macula Multi
- Macula Radial
- Disc Map
- Disc Radial

Anterior Scan Patterns

- Cornea line
- Cornea cross
- Cornea radial
- ACA line

The Mirante includes scanning laser ophthalmoscope (SLO) functions as well as the OCT functions. The SLO component uses a confocal scanning system for image capture. The imaging light emitted from the laser oscillator passes through the hole mirror and enters the patient's eye. The reflected light is reflected by the hole mirror and the signal is obtained by the detector.

A resonant mirror and a galvanometer mirror placed in the imaging optical path scan the imaging light in the XY direction to obtain a flat surface image.

Indications for Use

Scanning Laser Ophthalmoscope Mirante [SLO/OCT Model]

The Mirante SLO/OCT with scanning laser ophthalmoscope and optical coherence tomography function and with Image Filing Software NAVIS-EX is a non-contact system for imaging the fundus and for axial cross sectional imaging of ocular structures. It is indicated for in vivo imaging and measurement of:

• the retina, retinal nerve fiber layer, optic disc, and

• the anterior chamber and cornea (when used with the optional anterior segment OCT adapter)

and for color, angiography, autofluorescence, and retro mode imaging of the retina as an aid in the diagnosis and management. The Image Filing Software NAVIS-EX is a software system intended for use to store, manage, process, measure, analyze and display patient data and clinical information from computerized diagnostic instruments through networks. It is intended to work with compatible NIDEK ophthalmic devices.

Scanning Laser Ophthalmoscope Mirante [SLO Model]

The Mirante SLO with scanning laser ophthalmoscope function and with Image Filing Software NAVIS-EX is a non-contact system for imaging the fundus. It is indicated for color, angiography, auto-fluorescence, and retro mode imaging of the retina as an aid in the diagnosis and management. The Image Filing Software NAVIS-EX is a software system intended for use to store, manage, process, measure, analyze and display patient data and clinical information from computerized diagnostic instruments through networks. It is intended to work with compatible NIDEK ophthalmic devices.

Statement of Substantial Equivalence

Nidek believes that the Nidek Mirante described in this notification and for use under the conditions of the proposed labeling is substantially equivalent to legally marketed predicate devices. These are Class II medical devices and include the Avanti OCT cleared in K180660 and the OPTOS P200DTx cleared in K142897.

Optical coherence tomography (OCT)

The Mirante is substantially equivalent to the Avanti for the intended use for imaging and measurements of anterior and posterior ocular structures. The Mirante has virtually the same intended use as Avanti (K180660) with the exception that the Mirante does not include a normative database.

The principle of operation is identical in that both devices employ a non-invasive, non-contact low-coherence interferometry technique [specifically, spectral domain optical coherence tomography (SD-OCT)] to generate high-resolution cross-sectional images of internal ocular tissue microstructures by measuring optical reflections from tissue. Both provide cross sectional images of the anterior and posterior structures of the eye (i.e., cornea and retina, including the ganglion and retinal nerve fiber layers).

Scanning Laser Ophthalmoscope (SLO)

The Mirante is substantially equivalent to the OPTOS P200DTx for the intended use as a widefield and retinal fluorescence and autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases and disorders that manifest in the retina. The Mirante has the same intended use as OPTOS P200DTx (K142897).

The principle of operation is identical in that both devices employ a confocal scanning system for image capture. The imaging light emitted from the laser oscillator passes through the hole mirror and enters the patient's eye. The reflected light is reflected by the hole mirror and the signal is obtained by the detector.

There are minor differences in technological characteristics between the Mirante and the predicate devices that do not raise questions of safety or effectiveness.

Discussion

Bench testing has been performed to demonstrate that the Mirante device performs as intended and is substantially equivalent to the predicate devices, Avanti (K180660) and OPTOS P200DTx

(K142897), with respect to imaging and measurement of ocular structures. Both devices comply with recognized consensus standards regarding electrical safety, optical safety and biocompatibility. The system level testing with software version 1.22 was conducted with passing results.

Performance testing included OCT and SLO system testing, optical safety testing, and Usability testing. The performance testing demonstrated that the device satisfies the performance requirements specified for its intended use and is equivalent to the relevant performance characteristics of the comparative predicate device.

Therefore, based on the same intended use and similar technological characteristics with substantial equivalence to the predicate devices confirmed with performance testing, the Mirante is technologically and functionally equivalent to the predicate devices, Avanti (K180660) and OPTOS P200DTx (K142897). The differences between the proposed device, Mirante, and the predicate devices are insignificant and do not raise new issues of safety or effectiveness of the device.

The Comparison Table of Technological Characteristics follows.

Table 1: Comparison Table of Technological Characteristics – Mirante

	Test Device	Primary Predicate Device	Secondary Predicate Device	Discussion
Device Name	Mirante SLO/OCT model with NAVIS-EX	Avanti	P200DTx	
510(k) Number		(K180660)	(K142897)	
Classification, Product Code	Class II, HLI, OBO, MYC	Class II, HLI, OBO	Class II, MYC	Same
Regulation number	21CFR 886.1570	21 CFR 886.1570	21 CFR 886.1570	Same
	(Ophthalmoscope, AC-Powered)	(Ophthalmoscope, AC-Powered)	(Ophthalmoscope, AC-Powered)	Same
Applicant	Nidek Co., Ltd.	Optovue, Inc.	Optos, Plc	
Indications for use	The Mirante SLO/OCT with scanning laser ophthalmoscope and optical coherence tomography function and with Image Filing Software NAVIS-EX is a non-contact system for imaging the fundus and for axial cross sectional imaging of ocular structures. It is indicated for in vivo imaging and measurement of: • the retina, retinal nerve fiber layer, optic disc, and • the anterior chamber and cornea (when used with the optional anterior segment OCT adapter) and for color, angiography, autofluorescence, and retro mode imaging of the retina as an aid in the diagnosis and management.	The Avanti is an optical coherence tomography system intended for the in vivo imaging, cross-sectional, and three-dimensional imaging and measurement of anterior and posterior ocular structures, including retina, retinal nerve fiber layer, ganglion cell complex (GCC), optic disc, cornea, corneal epithelia, corneal stroma, pachymetry, corneal power, and anterior chamber of the eye. With the integrated normative database, Avanti is also a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disc measurements in the human eye to a database of a known normal subjects. It is indicated for use as a diagnostic device to aid in the detection and management of ocular diseases.	The P200DTx scanning laser ophthalmoscope is indicated for use as a widefield and retinal fluorescence and autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases and disorders that manifest in the retina. It is also indicated for use as a widefield scanning laser ophthalmoscope for viewing choroidal circulation patterns that are illuminated using Indocyanine Green dye and for aiding in both the assessment of choroidal circulation and in the diagnosis of choroiditis or choroidal diseases.	Similar - All devices support imaging of the posterior and anterior segment of the eye. The Mirante does not include a integrated normative database. The indications for use of the NAVIS-EX have remained unchanged from the indications for use of the previously cleared NAVIS-EX.

		Test Device	Primary Predicate Device	Secondary Predicate Device	Discussion
		The Image Filing Software NAVIS-EX is a software system intended for use to store, manage, process, measure, analyze and display patient data and clinical information from computerized diagnostic instruments through networks. It is intended to work with compatible NIDEK ophthalmic devices.	The Avanti with the AngioVue software feature is indicated as an aid in the visualization of vascular structures of the retina and choroid in normal subjects, and in subjects with glaucoma and retinal diseases. The AngioAnalytics software feature of AngioVue is indicated for the measurement of vascular density, the foveal avascular zone, the thickness of retinal layers, and nerve fiber layer, and measurement of optic disc parameters in normal subjects, and in subjects with glaucoma and retinal diseases.		
OCT Function					
Principle	Retina cross-sectional observation and image capture	Spectral domain OCT	Spectral domain OCT	-	Same for the predicate device.
	Anterior segment cross-sectional observation and image capture	Spectral domain OCT	Spectral domain OCT		Same for the predicate device.
Light source wavelength		880 nm	840 nm	-	Similar value The difference does not result in any difference in OCT image quality that can affect diagnosis. Thus, the light source wavelength is considered to be substantially equivalent between the Mirante and the predicate device.
Scan rate (temporal resolution)		85,000 A-Scan/sec	70,000 A-Scan/sec	-	Similar The higher scan rate for the Test device does not affect the safety and efficacy as compared to the predicate

		Test Device	Primary Predicate Device	Secondary Predicate Device	Discussion
Resolution (Optical resolution)	Retina cross-sectional image capture	Retina cross-sectional observation Horizontal (X-Y) directions: 20 µm Depth (Z) direction: 7 µm	Horizontal: 15 µm（according to brochure） Depth: 5 µm		Similar The differences are not expected to affect the safety or effectiveness of the device.
	Anterior segment cross-sectional observation and image capture	Anterior segment cross-sectional observation (Optional) Horizontal (X-Y) directions: 30 µm Depth (Z) direction: 7 µm	Horizontal (X-Y) direction: Unknown Depth: 5 µm		Similar depth The horizontal resolution of the predicate device is unknown., however, resolution in the horizontal (X-Y) direction does not substantially affect the device effectiveness. The differences are not expected to affect the safety or effectiveness of the device
Angle of view	Retina cross-sectional image capture	Scan width: 3 mm to 16.5 mm, Scan depth: 2.1 mm	Scan width: 2 mm to 12 mm, Scan depth: 2 mm to 3 mm		Similar values The scan width and scan depth are considered to be substantially equivalent between the Mirante and the predicate device.
	Anterior segment cross-sectional image capture	Scan width: 2 to 8 mm, Scan depth: 2.1 mm	12 mm × 8 mm (Field of view) Maximum of 2.3mm (according to Operator's Manual)		Similar values The scan width and scan depth are considered to be substantially equivalent between the Mirante and the predicate device.
Display resolution	Retina cross-sectional image capture	Horizontal (X-Y) directions: 3 µm/pixel Depth (Z) direction 4 µm/pixel	unknown		predicate information unknown Because the length per pixel of the Mirante is smaller than the optical resolution, this only contributes to the fineness of the depicted structures and the amount of information obtained for diagnosis remains unchanged. Therefore, this is not considered to be an issue for safety or effectiveness for the Mirante.
	Anterior segment cross-sectional image capture	Horizontal (X-Y) directions 2 µm/pixel Depth (Z) direction 4 µm/pixel	unknown		

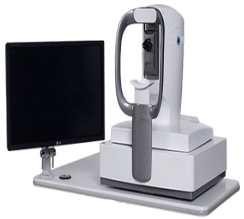
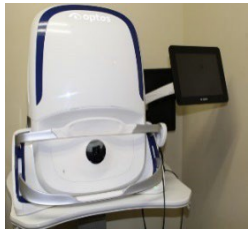
		Test Device	Primary Predicate Device	Secondary Predicate Device	Discussion
Required pupil diameter		2.5 mm in diameter (3 mm in diameter or larger is recommended.)	2.3 mm		Similar values The required pupil diameter is considered to be substantially equivalent between the Mirante and the predicate OCT device.
Sensitivity		Regular, Fine, Ultrafine	unknown		The predicate information is unknown The [Fine] or [Ultra Fine] setting may allow capturing of proper cross sectional (OCT) images even though only OCT images with lower quality were captured for the eye with the [Regular] setting". The provision of the [Fine] or [Ultra Fine] setting does not improve the effectiveness. The increase in the status of target eyes that Mirante can deliver the basic performance (or capture the OCT images) will act to reduce the risk of misdiagnosis due to insufficient information, and will raise no new safety concerns.
OCT Scan Pattern	Retinal scan pattern	Macula Line	Line		Similar functions Although the scan patterns are slightly different in terms of names and variations, both the Mirante and the predicate device have similar scan patterns.
		Macula Cross	Cross Line		
		Macula Map	Grid		
		Macula Multi	Raster		
		Macula Radial	Retina Map		
		Disc Map	3D Retina		
		Disc Radial	3D Widefield		
			3D Widefield With MCT		
			Radial Lines		
			Enhances HD Line		
			GCC		
			ONH		
			3D Disc		
			3D Clinical		
	Anterior scan pattern	Cornea line	Pachymetry		
		Cornea cross	Pachymetry Wide		

		Test Device	Primary Predicate Device	Secondary Predicate Device	Discussion
		Cornea radial	Pachymetry + Corneal Power		
		ACA line	Cornea Line		
			Cornea Cross Line		
			Angle		
			3D Cornea		
Choroidal mode (EDI)		Yes	Yes		Same
Position of retinal layer borderline as segmentation algorithms		ILM NFL/GCL IPL/INL RPE/BM	ILM NFL IPL RPE		Same
Position of corneal layer borderline as segmentation algorithms		Anterior Posterior	Anterior Posterior		Same
Anterior segment imaging function					
Principal		SLO: Confocal laser scanning method	Monochrome CCD Camera		The devices use different methods to perform the function. These differences are not expected to have an impact on the device safety or efficacy.
Light source wavelength		IR (Infrared): 790 nm	NIR (Near Infrared): 735 nm LED		
Field of View		22.6 mm ±5% in diameter	12 mm × 8 mm		
SLO Function					
Principle		SLO: Confocal laser scanning method		SLO: Confocal laser scanning method	Same
Light source wavelength		Blue: 488 nm		Blue: 488 nm	The test device has similar light source wavelengths compared to the predicate device. The difference in wavelengths is considered not to cause substantial differences between the Mirante and the predicate device.
		Green: 532 nm		Green: 532 nm	
		Red: 670 nm		Red: 635 nm	
		IR (Infrared): 790 nm		IR (Infrared): 802 nm	
Resolving power		Regular angle		Unknown	

	Test Device	Primary Predicate Device	Secondary Predicate Device	Discussion
	Center:- - Horizontal direction: 32 lp/mm - Vertical direction: 50 lp/mm		Unknown	Mirante is considered to have the minimum resolving power required for fundus cameras. Thus, Mirante is considered to have substantially equivalent resolving power compared to fundus imaging devices on the market.
	50% Image height : 25 lp/mm			
	95% Image height: 16 lp/mm			
	Wide angle (Optional)			
	Center: - Horizontal direction: 17.5 lp/mm - Vertical direction: 28 lp/mm			
	50% Image height: 11 lp/mm			
	95% Image height: 5.4 lp/mm			
HD on/off	Available		None	The HD on/off function for reducing noises contributes to the convenience, not to the effectiveness. The presence of this function does not substantially affect the safety and effectiveness of the Mirante.
Angle of view	Regular angle: 60º		148º x 115º (external to eye)	The predicate devices have different references for the angel of view. This does not indicate a safety or efficacy issue with the test device Both the Mirante and the predicate device obtain equivalent information that is essentially necessary for diagnosis. Thus, the angle of view is considered to be substantially equivalent between the Mirante and the predicate device.
	Wide angle (Optional): 110º			
Required pupil diameter	Regular angle: 3.3 mm in diameter		2 mm	Similar requirements. No safety or efficacy impact.
(Fundus surface imaging function)	Wide angle (Optional): 3.3 mm in diameter			
Mode			Red Free	Similar modes. The test device has an I/R mode that is not present in the predicate.
	IR (refraction of Infrared light)			
	FA (fluorescein angiography using blue light)		FA	

		Test Device	Primary Predicate Device	Secondary Predicate Device	Discussion
		ICG (indocyanine green angiography using infrared light)		ICG	These differences are not expected to have an impact on the device safety or efficacy. The differences in SLO modes are considered not to affect the safety and effectiveness.
		FAF(fundus autofluorescence using blue or green light)		FAF	
		Color (using blue, green, and red light)		Color	
		Retro (This mode is to capture the image of retina that is illuminated from behind by infrared light scattered by choroid. This is a kind of Retro illumination method.)			
Image size	-	4096 × 4096, 2048 × 2048, 1536 × 1536, 1024 × 1024, 768 × 768, 512 × 512		Optomap plus: 3900 pixels (W) x 3072 pixels (H) Optomap: 2600 pixels (W) x 2048 pixels (H)	Similar Mirante has both lower and higher pixel patterns than the predicate device. Thus, the resolution is considered to be substantially equivalent between the Mirante and the predicate device.
Panorama		Yes	unknown		predicate information unknown The function allows Mirante to captures images for panorama image composition for viewing so that NAVIS-EX overlaps and composes multiple fundus images captured at different angles. This function increases the convenience, but does not increase the amount of information. This function is considered not to affect the safety and effectiveness.
Others					
Focus range/Focus compensation		- 15D to +15D（V.D.=12）	- 15D to +12D	-12D to +7D	Similar The differences do not affect the safety and effectiveness in clinical use.
Working distance	Fundus surface / Anterior segment	19.0 mm ±1mm (between objective lens and cornea)	Fundus Imager: 22 mm	Unknown	Similar

		Test Device	Primary Predicate Device	Secondary Predicate Device	Discussion
	front imaging function	Wide Angle (Optional): 9.0 mm ±1mm or more	Corneal Imager: 13 mm		These specifications are related to convenience in image capture but do not affect the safety and effectiveness.
	OCT	19.0 mm ±1mm (between objective lens and cornea)	22 mm		
		15.4 mm ±1 mm (Anterior segment cross-sectional image capture)			
Movement range	Main body (vertical movement)	30 mm	25 mm	Unknown	
	Main body (horizontal movement)	Forward and backward: 165 mm	X: 100 mm	Unknown	
		Left and right: 110 mm	Y: 85 mm		
	Chinrest (vertical movement)	80 mm	65 mm	Unknown	
Dimensions and weight	Main Body	[SLO/OCT model]	380 (W) × 524 (D) × 499 to 531(H) mm	550(W) × 550(D) × 608 to 632(H) mm	
		345 (W) × 548 (D) × 527 to 557 (H) mm (Image capturing unit)	34kg	34 kg	
		23 kg (Image capturing unit)			
		203 (W) × 424 (D) × 438 (H) mm (Control box)			
		20 kg (Control box)			
		[SLO model]			
		345 (W) × 548 (D) × 527 to 557 (H) mm (Image capturing unit)			
		22 kg (Image capturing unit)			
		203 (W) × 424 (D) × 438 (H) mm (Control box)			
		16 kg (Control box)			
	Isolation Transformer	130 (W) × 220 (D) × 125 (H) mm	142(W) × 564(D) × 239(H) mm		
		7.0 kg	15kg		
	Computer	177 (W) × 480 (D) × 426 (H) mm	210(W) × 477(D) × 430(H) mm		
		19 kg (Computer)	18kg		
		508 (W) × 56 (D) × 325 (H) mm	(without monitor)		

		Test Device	Primary Predicate Device	Secondary Predicate Device	Discussion
		4.0 kg (Computer monitor)			
Power supply specifications	Main Body	AC100V-240V150VA, 50/60Hz	AC110VAC and 230VAC, 1.8A, 50/60Hz	100-240Vac, 50/60Hz	
	Isolation Transformer	AC100V1000VA, 50/60Hz	AC110-240 VAC, 1.8A, 50/60Hz		
	Computer	400 W (Computer) 27 W (Computer monitor)	unknown		
Others	Auto shot	Yes (OCT)	None	Yes	Similar
	Eye Tracer	Yes	Yes	Unknown	Same
	Color Fundus image capture mode	Pseudo Color	None	Pseudo Color	Similar
	External fixation lamp	Yes	Yes	None	Same
Appearance					

With regards to the technical differences between the Mirante, the RTVue XR Avanti and the P200DTx in the Comparison Table above the clinical and non-clinical testing demonstrates that the differences do not raise any new questions about safety and effectiveness. Summaries of the non-clinical and clinical testing are provided in the following sections.

The following are the differences in measurement and analysis between the devices:

Substantial Equivalence Discussion for the Nidek Mirante per the 510(k) Decision-Making Flowchart

Q1. Are the predicate device(s) legally marketed?

Yes, the predicate device Avanti OCT was cleared in K180660 and the OPTOS P200DTx SLO was cleared in K142897.

Q2. Do the devices have the same intended use?

Yes, the Mirante OCT/SLO has the same intended use as the predicate devices except that the Mirante does not include a normative database. Both Mirante and Avanti are ophthalmic imaging devices for viewing the fundus and anterior segment structures using optical coherence tomography. Avanti is provided with a normative database, while Mirante is not. Absence of the normative database that is a useful tool in diagnosis after fundus image capture does not impair the functions as an ophthalmic imaging device.

Q3. Do the devices have the same technological characteristics?

No, based on the information available the Mirante has different technological characteristics when compared to the Avanti OCT.

No, based on the information available the Mirante has different technological characteristics when compared to the OPTOS P200DTx SLO.

The differences in OCT that are found are include:

- Light source wavelength:

The difference in interference signal emission that is ascribed to the difference in wavelength (40 nm) does not result in any difference in OCT image quality that can affect the diagnosis, considering that resolution of OCT in the Z (depth) direction is on the order of micrometer. Thus, the light source wavelength is considered to be substantially equivalent between the Mirante and the predicate device.

- Scan rate (temporal resolution):

The Mirante has a higher scan rate 85,000 A-scan/second versus 70,000 A-scan/second. The higher scan rate results in the time for scanning of 1.54 seconds at 85000 A-scan/sec versus 1.87 seconds at 70,000 A-scan/sec resulting in a difference of less than 0.4 seconds when A-Scan is set to 1024 and B-Scan is set to 128. The slightly decreased imaging time with the Mirante is considered to be substantially equivalent to the predicate device.

- Resolution (Optical resolution):

(a) **Retina cross-sectional image capture**. The Mirante has a lower optical resolution in the horizontal (X-Y) direction, but the reduced resolution of 20 μm does not decrease the essential information for diagnosis.

Resolution in the depth (Z) direction was verified to be less than or equal to 7 μm. The actual measured values ranged from 6.62 to 6.94 μm in air and from 4.78 to 5.01 μm when converted to

the values in the eye. This means that the resolution in the Z direction is approximately 5 μm in the eye, which is equivalent to the resolution in the depth (Z) direction of the predicate device.

Thus, the resolution in the depth direction is considered to be substantially equivalent between the Mirante and the predicate device.

(b) **Anterior segment cross-sectional observation and image capture**. The horizontal resolution of the predicate device is unknown, however, resolution in the horizontal (X-Y) direction does not substantially affect the device effectiveness.

Resolution for the Mirante in the depth (Z) direction was verified to be less than or equal to 7 μm. The actual measured values ranged from 6.89 to 6.98 μm in air and from 4.98 to 5.04 μm when converted to the values in the eye. This means that the resolution in the Z direction is approximately 5 μm in the eye, which is equivalent to the resolution in the depth (Z) direction of the predicate device. Thus, the resolution in the depth direction is considered to be substantially equivalent between the Mirante and the predicate device.

- Angle of View:

(a) **Retina cross-sectional image capture**. The Mirante has a wider scan width than the predicate device, but the wider scan width does not substantially increase the effectiveness. The Mirante has a shorter scan depth than the predicate device by 0.9 mm. The depth of 2.1 mm corresponds to more than 5 times the thickness of the retina, which is a sufficient scan depth for diagnosis and the difference does not decrease the substantial effectiveness. Thus, the scan width and scan depth are considered to be substantially equivalent between the Mirante and the predicate device.

(b) **Anterior segment cross-sectional image capture**. Mirante has a shorter scan width but the width is sufficient for capturing in one image a range from a cornea center to a corneal peripheral part or from the corneal limbus to the proximity of pupillary edge at the iris that is an important part for diagnosis, and the difference between Mirante and the predicate device does not decrease the substantial effectiveness.

The Mirante has a shorter scan depth than Avanti by 0.2 mm. The depth of 0.2 mm is about 4 times as thick as the cornea and is sufficient for measuring the anterior chamber angle, and the difference does not decrease the substantial effectiveness. Thus, the scan width and scan depth are considered to be substantially equivalent between the Mirante and the predicate device.

- Display resolution:

The predicate information for this point is unknown. Because the length per pixel of the Mirante is smaller than the optical resolution, this only contributes to the fineness of the depicted structures and the amount of information obtained for diagnosis remains unchanged. Therefore, this is not considered to be an issue for safety or effectiveness for the Mirante.

- Required pupil diameter:

Although the required pupil diameter of Mirante is larger than that of Avanti, it is assumed that the pupils of most of the patients would be larger than the required pupil diameter under the intended environment. An OCT is intended to be used in a darkened room or half-darkened room and pupils open to an average of 3.24 mm under illumination of 4.00 lux and 4.05 mm under illumination of 0.40 lux. Thus, the required pupil diameter is considered to be substantially equivalent between the Mirante and the predicate OCT device.

- Sensitivity: predicate information for this function is unknown.

[Regular] "OCT Sensitivity" performs high-speed image capture with standard OCT sensitivity, while [Fine] or [Ultra Fine] setting allows a Signal Strength Index (SSI) value higher than that

obtained respectively with [Regular] or [Fine] by increasing the OCT sensitivity. The [Fine] or [Ultra Fine] setting may allow capturing of proper cross sectional (OCT) images even though only OCT images with lower quality were captured for the eye with the [Regular] setting.

There are cases where the device does not fully exert its basic performance to capture proper OCT images. Using the [Fine] or [Ultra Fine] setting covers those cases to some extent. In other words, using those settings expands the range where the device fully exerts its effectiveness.

Thus, the provision of the [Fine] or [Ultra Fine] setting does not improve the effectiveness. The increase in the status of target eyes that Mirante can deliver the basic performance (or capture the OCT images) will act to reduce the risk of misdiagnosis due to insufficient information, and will raise no new safety concerns.

- OCT Scan Patterns:

Although scan patterns are slightly different in terms of names and variations, both the Mirante and the predicate device have similar scan patterns.

- Anterior Segment Imaging Function:

The anterior segment imaging function acquires images used to show the position to which the anterior segment OCT image corresponds, and any essential difference lies in the presence or absence of this function itself; detailed specifications do not affect the essence of this function. Thus, the difference in principle is considered not to cause substantial differences between the Mirante and the predicate device.

The differences in SLO that are found are minor and include:

- Light source wavelength:

Red and infrared wavelengths are different between Mirante and the predicate device. Theoretically, different wavelengths reach different depths in structure but do not cause differences in observation for images related to diagnosis. Although chromatic aberration is also different between the Mirante and the predicate device, this is corrected respectively during color composition and alignment, and also does not cause differences in observation for images related to diagnosis. Thus, the difference in wavelengths is considered not to cause substantial differences between the Mirante and the predicate device.

- Resolving Power:

The predicate device resolving power is unknown. The Mirante is considered to have the minimum resolving power required for fundus cameras such as previously cleared AFC-330 (K113451), taking into account the reduction associated with the increased angle of view:

There are no international standards, guidelines, or other official criteria applicable to the optical performance of fundus SLOs. For this reason, NIDEK referred to the requirements for resolving power in ISO 10940:2009 for fundus cameras that are also fundus imaging devices to verify the specifications for resolving power in SLO bench testing provided in Appendix 8_1_34.

ISO 10940:2009, Section 4.2 requires the following resolving power:

Angle of view >30

Center ≧ 60 lp/mm

Center ≧ 40 lp/mm

Periphery ≧ 25 lp/mm

In addition, in general, it is clear that optical performance deteriorates as the angle of view

increases.

NIDEK assumed that the above criteria in ISO 10940:2009 to be the minimum requirement for the angle of view of 30°.

In consideration that optical performance decreases as the angle of view increases and based on assumption that the resolving power is inversely proportional to the angle of view for the above criteria in the standard, and the value obtained by multiplying the inverse of the ratio of the angle of view is assumed to be the criteria of resolving power that corresponds to the angle of view for fundus SLOs.

Based on this assumption, the criteria of resolving power with a normal angle of view of 60° for Mirante are calculated as follows:

Center: 60 lp/mm x 30/60 = 30 lp/mm

Middle: 40 lp/mm x 30/60 = 20 lp/mm

Periphery: 25 lp/mm × 30/60 = 12.5 lp/mm

The resolving powers of Mirante with the normal angle of view of Mirante meet the criteria as described on the left:

The criteria of resolving power with a wider angle of 110° for Mirante are calculated as follows:

Center: 60 lp/mm × 30/110≒16.4 lp/mm

Middle: 40 lp/mm × 30/110≒10.9 lp/mm

Periphery: 25 lp/mm × 30/110≒6.8 lp/mm

The resolving powers of the Mirante with a wider angle of view meet the criteria for the center and middle areas meet the criteria as described on the left, while it does not slightly meet the criterion for the periphery.

The eyeball is spherical, and the wider the angle of view, the greater the distortion in the periphery.

With an angle of view of 110°, the periphery is close to the equatorial plane and distortion is close to the maximum. Although the resolution in the periphery may not meet the criterion, this is considered to have no significant impact.

Thus, Mirante is considered to have substantially equivalent resolving power compared to fundus imaging devices on the market.

- HD on/off:

This is available for the Mirante but not available for the predicate. The HD on/off function for reducing noises contributes to the convenience, not to the effectiveness. This function is not necessarily essential if a high-quality image is obtained at a time. The presence of this function does not substantially affect the safety and effectiveness of the Mirante.

- Angle of View:

Mirante has a smaller angle of view than the predicate device both in normal image capture and wide-field image capture. However, both the Mirante and the predicate device have a 110 to 220-degree ultra-wide angle field of view that is defined as an image of the far periphery of the retina, including the anterior edge of the vortex vein ampulla and beyond. Both the Mirante and the predicate device obtain equivalent information that is essentially necessary for diagnosis. Thus, the angle of view is considered to be substantially equivalent between the Mirante and the

predicate device.

- Required pupil diameter:

Although the required pupil diameter of Mirante is larger than that of the predicate device, it is assumed that the pupils of most of the patients would be larger than the required pupil diameter under the intended environment. An SLO is intended to be used in a darkened room or half-darkened room and pupils open to an average of 3.24 mm under illumination of 4.00 lux and 4.05 mm under illumination of 0.40 lux. Thus, the required pupil diameter is considered to be substantially equivalent between the Mirante and the predicate OCT device.

- Mode:

Both Mirante and the predicate device have color imaging and fluorescence imaging functions. Although Mirante has infrared light (IR) imaging and retro mode imaging functions, but from a diagnostic standpoint, the information provided by IR images does not essentially exceed that of color SLO images. However, it is essentially a high-contrast monochromatic imaging mode. The retro mode imaging differs from the other imaging modes in its principle; the mode specializes in contrast enhancement and is essentially a high-contrast monochromatic imaging mode.

The differences in SLO modes are considered not to affect the safety and effectiveness.

- Image Size:

Mirante has both lower and higher pixel patterns than the predicate device.

With the setting of 4096 × 4096 pixels for the Mirante, which is a higher pixel number than Optomap plus of the predicate device, the length per pixel is approximately 3.25 μm, which is a smaller scale than the resolution. For this reason, smooth and "easy-to-see" images are obtained whose contribution is limited to the convenience because the fineness of the structures that can be depicted remains unchanged and the amount of obtained information for diagnosis remains unchanged. Thus, the resolution is considered to be substantially equivalent between the Mirante and the predicate device.

- Panorama:

Whether the predicate device is provided with this function is unknown. The function allows Mirante to capture images for panorama image composition for viewing so that NAVIS-EX overlaps and composes multiple fundus images captured at different angles. The function is equivalent to displaying multiple images captured at different angles at a time. This function increases the convenience but does not increase the amount of information. The presence or absence of this function is considered not to affect the safety and effectiveness.

- Focus range/Focus compensation:

Diopter correction compensates for the refractive errors of the patient's eye. Mirante has a wider range of focus for patients, and can target the patients with wider range of refractive errors but this does not affect the safety and effectiveness in clinical use.

- Working distance:

These specifications are related to convenience in image capture but do not affect the safety and effectiveness of the device.

Therefore, the minor differences between the subject device and the predicate devices do not raise new questions of safety or effectiveness. The Nidek Mirante is as safe and effective as its predicate devices, and thus, may be considered substantially equivalent.

Conclusion

The Nidek Mirante SLO/OCT has the same intended use and similar indications for use, technological characteristics, and principles of operation as the previously cleared predicates. A substantial equivalence chart comparing the similarities and differences between the subject device and its predicate device demonstrates substantial equivalence.

Mirante SLO only

Scanning Laser Ophthalmoscope (SLO)

The Mirante is substantially equivalent to the OPTOS P200DTx for the intended use as a widefield and retinal fluorescence and autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases and disorders that manifest in the retina. The Mirante has the same intended use as OPTOS P200DTx (K142897).

The principle of operation is identical in that both devices employ a confocal scanning system for image capture. The imaging light emitted from the laser oscillator passes through the hole mirror and enters the patient's eye. The reflected light is reflected by the hole mirror and the signal is obtained by the detector.

There are minor differences in technological characteristics between the Mirante and the predicate devices that do not raise questions of safety or effectiveness.

Discussion

Bench testing has been performed to demonstrate that the Mirante device performs as intended and is substantially equivalent to the predicate device OPTOS P200DTx (K142897) with respect to imaging and measurement of ocular structures. Both devices comply with recognized consensus standards regarding electrical safety, optical safety and biocompatibility. The system level testing with software version 1.22 was conducted with passing results.

Performance testing included SLO system testing, optical safety testing, and Usability testing. The performance testing demonstrated that the device satisfies the performance requirements specified for its intended use and is equivalent to the relevant performance characteristics of the comparative predicate device.

Therefore, based on the same intended use and similar technological characteristics and with substantial equivalence to the predicate devices confirmed with performance testing, the Mirante is technologically and functionally equivalent to the predicate device, OPTOS P200DTx (K142897). The differences between the proposed device, Mirante, and the predicate device are insignificant and do not raise new issues of safety or effectiveness of the device.

The Comparison Table of Technological Characteristics follows.

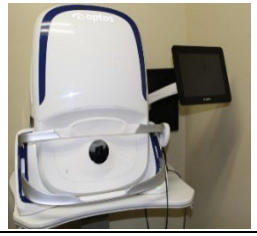
Table 2: Comparison Table of Technological Characteristics – Mirante SLO

	Test Device	Predicate Device	Discussion
Device Name	Mirante SLO with NAVIS-EX	P200DTx	
510(k) Number		(K142897)	
Classification, Product Code	ClassII, HLI, OBO, MYC	ClassII, MYC	Same
Regulation number	21CFR 886.1570	21 CFR 886.1570	Same
	(Ophthalmoscope, AC-Powered)	(Ophthalmoscope, AC-Powered)	Same
Applicant	Nidek Co., Ltd.	Optos, Plc	
Intended Use	The Mirante SLO with scanning laser ophthalmoscope function and with Image Filing Software NAVIS-EX is a non-contact system for imaging the fundus. It is indicated for color, angiography, auto-fluorescence, and retro mode imaging of the retina as an aid in the diagnosis and management. The Image Filing Software NAVIS-EX is a software system intended for use to store, manage, process, measure, analyze and display patient data and clinical information from computerized diagnostic instruments through networks. It is intended to work with compatible NIDEK ophthalmic devices.	The P200DTx scanning laser ophthalmoscope is indicated for use as a widefield and retinal fluorescence and autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases and disorders that manifest in the retina. It is also indicated for use as a widefield scanning laser ophthalmoscope for viewing choroidal circulation patterns that are illuminated using Indocyanine Green dye and for aiding in both the assessment of choroidal circulation and in the diagnosis of choroiditis or choroidal diseases.	Similar
SLO Function			
Principle	SLO: Confocal laser scanning method	SLO: Confocal laser scanning method	Same
Light source wavelength	Blue: 488 nm	Blue: 488 nm	The test device has similar light source wavelengths compared to the predicate device. The difference in wavelengths is considered not to cause substantial differences between the Mirante and the predicate device.
	Green: 532 nm	Green: 532 nm	
	Red: 670 nm	Red: 635 nm	
	IR (Infrared): 790 nm	IR (Infrared): 802 nm	
Resolving power	Regular angle	Unknown	Mirante is considered to have the minimum resolving power required for fundus cameras. Thus, Mirante is considered to have substantially equivalent resolving power compared to fundus imaging devices on the market.
	Center: - Horizontal direction: 32 lp/mm - Vertical direction: 50 lp/mm	Resolving power	
	50% Image height: 25 lp/mm		
	95% Image height: 16 lp/mm		

	Wide angle (Optional)		

	Test Device	Predicate Device	Discussion
	Center: - Horizontal direction: 17.5 lp/mm - Vertical direction: 28 lp/mm		
	50% Image height: 11 lp/mm		
	95% Image height: 5.4 lp/mm		
HD on/off	Available	None	The HD on/off function for reducing noises contributes to the convenience, not to the effectiveness. The presence of this function does not substantially affect the safety and effectiveness of the Mirante.
Angle of view	Regular angle: 60º	148º x 115º (external to eye)	The predicate devices have different references for the angel of view. This does not indicate a safety or efficacy issue with the test device Both the Mirante and the predicate device obtain equivalent information that is essentially necessary for diagnosis. Thus, the angle of view is considered to be substantially equivalent between the Mirante and the predicate device.
	Wide angle (Optional): 110º		
Required pupil diameter	Regular angle: 3.3 mm in diameter	2mm	Similar requirements. No safety or efficacy impact.
(Fundus surface imaging function)	Wide angle (Optional): 3.3 mm in diameter		
Mode		Red Free	Similar modes. The test device has an I/R mode that is not present in the predicate. These differences are not expected to have an impact on the device safety or efficacy. The differences in SLO modes are considered not to affect the safety and effectiveness.
	IR (refraction of Infrared light)		
	FA(fluorescein angiography using blue light)	FA	
	ICG (indocyanine green angiography using infrared light)	ICG	
	FAF(fundus autofluorescence using blue or green light)	FAF	
	Color (using blue, green, and red light)	Color	
	Retro (This mode is to capture the image of retina that is illuminated from behind by infrared light scattered by choroid. This is a kind of retroillumination method.)		

		Test Device	Predicate Device	Discussion
Image size		4096 × 4096, 2048 × 2048, 1536 × 1536, 1024 × 1024, 768 × 768, 512 × 512	Optomap plus: 3900 pixels (W) x 3072 pixels (H) Optomap: 2600 pixels (W) x 2048 pixels (H)	Similar Mirante has both lower and higher pixel patterns than the predicate device. Thus, the resolution is considered to be substantially equivalent between the Mirante and the predicate device.
Panorama		Yes		predicate information unknown The function allows Mirante to captures images for panorama image composition for viewing so that NAVIS-EX overlaps and composes multiple fundus images captured at different angles. This function increases the convenience, but does not increase the amount of information. This function is considered not to affect the safety and effectiveness.
Others				
Focus range/Focus compensation		- 15D to +15D （V.D.=12）	-12D to +7D	Similar The differences do not affect the safety and effectiveness in clinical use.
Working distance	Fundus surface / Anterior segment front imaging function	19.0 mm ±1mm (between objective lens and cornea)	Unknown	predicate information unknown These specifications are related to convenience in image capture but does not affect the safety and effectiveness.
		Wide Angle (Optional): 9.0 mm ±1mm or more		
Movement range	Main body (vertical movement)	30 mm	Unknown	
	Main body (horizontal movement)	Forward and backward: 165 mm	Unknown	
		Left and right: 110 mm		
	Chinrest (vertical movement)	80 mm	Unknown	
Dimensions and weight	Main Body	[SLO/OCT model]	550(W) × 550(D) × 608 to 632(H) mm	
		345 (W) × 548 (D) × 527 to 557 (H) mm (Image capturing unit)	34 kg	
		23 kg (Image capturing unit)		
		203 (W) × 424 (D) × 438 (H) mm (Control box)		
		20 kg (Control box)		
		[SLO model]		

		Test Device	Predicate Device	Discussion
		345 (W) × 548 (D) × 527 to 557 (H) mm (Image capturing unit)		
		22 kg (Image capturing unit)		
		203 (W) × 424 (D) × 438 (H) mm (Control box)		
		16 kg (Control box)		
	Isolation Transformer	130 (W) × 220 (D) × 125 (H) mm		
		7.0 kg		
	Computer	177 (W) × 480 (D) × 426 (H) mm		
		19 kg (Computer)		
		508 (W) × 56 (D) × 325 (H) mm		
		4.0 kg (Computer monitor)		
Power supply specifications	Main Body	AC100V-240V150VA, 50/60Hz	100-240Vac, 50/60Hz	
	Isolation Transformer	AC100V1000VA, 50/60Hz		
	Computer	400 W (Computer)		
		27 W (Computer monitor)		
Others	Auto shot	Yes (OCT)	Yes	Similar
	Eye Tracer	Yes	Unknown	predicate information unknown
	Color Fundus image capture mode	Pseudo Color	Pseudo Color	Similar
	External fixation lamp	Yes	None	Same
Appearance				

With regards to the technical differences between the Mirante, the Avanti and the P200DTx in the Comparison Table above the clinical and non-clinical testing demonstrates that the differences do not raise any new questions about safety and effectiveness.

Substantial Equivalence Discussion for the Nidek Mirante per the 510(k) Decision-Making Flowchart

Q1. Are the predicate device(s) legally marketed?

Yes, the predicate device Avanti OCT was cleared in K180660 and the OPTOS P200DTx SLO was cleared in K142897.

Q2. Do the devices have the same intended use?

Yes, the Mirante OCT/SLO has the same intended use as the predicate devices except that the Mirante does not include a normative database.

Q3. Do the devices have the same technological characteristics?

No, based on the information available the Mirante has different technological characteristics when compared to the OPTOS P200DTx SLO. The differences found are minor and are summarized in Section 9.1.3 above.

However, the minor differences between the subject device and the predicate device do not raise new questions of safety or effectiveness. The Nidek Mirante is as safe and effective as its predicate device, and thus, may be considered substantially equivalent.

1.1.1. Conclusion

The Nidek Mirante has the same intended use and similar indications for use, technological characteristics, and principles of operation as the previously cleared predicates. A substantial equivalence chart comparing the similarities and differences between the subject device and its predicate device demonstrates substantial equivalence.

Scanning Laser Ophthalmoscope (SLO)

The Mirante is substantially equivalent to the OPTOS P200DTx for the intended use as a widefield and retinal fluorescence and autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases and disorders that manifest in the retina. The Mirante has the same intended use as OPTOS P200DTx (K142897).

The principle of operation is identical in that both devices employ a confocal scanning system for image capture. The imaging light emitted from the laser oscillator passes through the hole mirror and enters the patient's eye. The reflected light is reflected by the hole mirror and the signal is obtained by the detector.

There are minor differences in technological characteristics between the Mirante and the predicate devices that do not raise questions of safety or effectiveness.

Performance testing, including both bench testing and clinical testing, demonstrate substantial equivalence.

Therefore, based on the same intended use and similar technological characteristics with substantial equivalence to the predicate devices confirmed with performance testing, the Mirante is technologically and functionally equivalent to the predicate devices, RTVue XR Avanti (K180660) and OPTOS P200DTx (K142897). The differences between the proposed device, Mirante, and the predicate device are insignificant and do not raise new issues of safety or effectiveness of the device. The Nidek Mirante is as safe and effective as its predicate devices, and thus, may be considered substantially equivalent.

Performance Testing

The Mirante has been verified for performance and functionality to assure conformance to the requirements for its

basic intended use.

The Mirante's compliance to electrical safety, light safety and biocompatibility has been established. The software development lifecycle and the associated verification and validation activities have no unresolved major or critical bugs. A list of testing conducted included:

- Medical electrical equipment - Part 1: General requirements for basic safety and essential performance: AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
- Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests: IEC 60601-1-2:2014
- Medical device software - Software life cycle processes: IEC 62304: Edition 1.1 2015-06
- Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]: IEC 62366-1: Edition 1.0 2015-02
- American National Standard for Ophthalmics - Light Hazard Protection for Ophthalmic Instruments: ANSI Z80.36-2016
- Safety of laser products - Part 1: Equipment classification, and requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]: IEC 60825-1: Edition 2.0 2007-03
- Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments: ISO 15004-1: First edition 2006-06-01
- Health software - Part 1: General requirements for product safety: IEC 82304-1 Edition 1.0 2016-10

The biocompatibility of the skin contacting materials was previously established for the SL-2000 (K163564) and the materials are identical to those previously approved.

Software documentation has been prepared and submitted for a "moderate" Level of Concern device in accordance with FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.* The device software was verified and validated to support the proposed indications for use according to IEC 62304:2015 *Medical device software – Software life cycle processes* and FDA's *General Principles of Software Validation; Final Guidance for Industry and FDA Staff*.

Risk Analysis

The device and the device software have been assessed to make sure all the risks were sufficiently mitigated according to the intended use. Identification of the associated hazards has been performed in order to evaluate, estimate and control the associated risks in accordance with EN ISO 14971 *Application of risk analysis to medical devices*.

Clinical Performance

Clinical performance testing was conducted to demonstrate substantial equivalence. A prospective, comparative clinical study was conducted in compliance with 21 CFR parts 50, 56, and 812 at one clinical site in the United States. The clinical testing was not subject to the regulations under 21 CFR 56.104 or 56.105. The primary purpose of the clinical study was to assess agreement and precision of the Nidek Mirante OCT in comparison with Avanti OCT and to assess image quality of Nidek Mirante OCT Anterior Chamber Angle image compared to Avanti. Additionally, the Nidek Mirante SLO image quality was compared to the OPTOS P200DTx. The secondary purpose was to evaluate any adverse event found during the clinical study.

Subject Disposition:

A total of 170 subjects were enrolled in the study and included in the Safety Analysis Set and Full Analysis Set. This included:

- 45 subjects in the Normal group,
- 46 subjects in the Glaucoma group,
- 47 subjects in the Retinal Disease group, and
- 32 subjects in the Corneal Disease group.

Of those, three subjects in the Glaucoma group discontinued due to a major protocol deviation of inclusion/exclusion and randomization category. A total of 167 subjects completed the study.

Demography and Baseline Characteristics:

The mean (standard deviation [SD]) age in the Full Analysis Set was:

- 44.9 (15.36) years for the normal eye subjects,
- 65.1 (9.20) years for the Glaucoma subjects,
- 69.7 (11.23) years for the Retinal Disease subjects, and
- 55.4 (15.09) years for the Corneal Disease subjects.

The overall mean age for all subjects was 59.2 (16.05) years, with the majority of subjects aged <65 years old (n = 96, 56.5%).

A total of 71 males and 99 females participated (41.8% and 58.2%, respectively) in this study, and the majority of subjects were white (n = 158, 92.9%) and not Hispanic or Latino (n = 159, 93.5%).

Iris color for all subjects included:

- blue (n = 51, 30.0%),
- brown (n = 73, 42.9%),
- hazel (n = 37, 21.8%),
- green (n = 8, 4.7%) and
- gray (n = 1, 0.6%).

Scan Acceptability:

A total of 169 subjects had acceptable scans, and 115 subjects had unacceptable scans (105 subjects for Mirante scans, 55 subjects for Avanti scans, and 9 subjects for Optos scans).

Scan acceptability was by a 2-step process where the device operator identified acceptable and unacceptable scans and then an Investigator image reviewer reviews the scans making the final determination of which scans were acceptable or unacceptable.

Effectiveness Results:

<u>Agreement Analyses</u>: Mirante / Avanti Analyses:

For the agreement analyses between Mirante and Avanti, agreement performance goals were met for [ILM-RPE/BM] and Disc Map RNFL Thickness for all parameters and each individual population.

Mean differences between Mirante and Avanti scans (Mirante – Avanti) were higher for the Mirante device for all populations for [ILM-RPE/BM] Thickness analysis, and were higher for most parameters, with the exception of Temporal, Superior, Nasal, Inferior, Temporal (TSNIT) Temporal in the All Subjects and Normal populations, for Disc Map RNFL Thickness.

For [ILM-RPE/BM] Thickness, Mirante is likely thicker by around 10-20 µm than Avanti due to the definition of lower line, where Mirante measures between RPE and BM while Avanti measure on RPE. Additionally, for the upper line, Mirante measure the upper line (vitreous side) of ILM whereas Avanti measure on ILM. For Disc Map – RFNL Thickness, Mirante is likely thicker (around 10 µm), with the exception of TSNIT Temporal, due to the difference of segmentation algorism of blood vessels area, especially large blood vessels, with Mirante measuring

line underside of blood vessels and Avanti crossing blood vessels. The exception of TSNIT Temporal being similar for both devices is because large blood vessels do not run in the Temporal area anatomically.

For Disc Map Optic Disc analysis, the Mirante scans had lower values compared to Avanti scans for Horizontal C/D Ratio and Vertical Cup-to-Disc (C/D) Ratio and higher values for Disc Area and Cup Area for the All Subjects population. Mirante had slightly similar mean differences for the Normal population and lower values for the Glaucoma population, compared to the Avanti scans. Agreement performance goals were met for all parameters and each individual population.

For Cornea Radial Central Corneal Thickness (CCT) analysis, the Mirante scans had higher mean differences than those of the Avanti device for the All Subjects, Normal, and Corneal Disease populations, but agreement performance goals were not met for the Normal and Corneal Disease populations for the CCT parameter.

Mirante is thicker by around 15 µm than Avanti due to the definition of upper and lower line, with Mirante measuring inside and outside of the cornea surface and Avanti measuring on the cornea surface. There is a 1 to 2-pixel difference for each on both sides, with one pixel at approximately 4 µm for Mirante and approximately 3 µm for Avanti.

Table 3: Summary of Limits of Agreement for All Configurations - [ILM-RPE/BM] Thickness - Nidek (Test) Mirante Macula Map (9 x 9 mm Tracing HD OFF) and Optovue (Predicate) Avanti Retina Map - [ILM- RPE/BM] Thickness Analysis Set

Subject Population Comparable Parameter	N	Nidek Mirante (Test)	Optovue Avanti (Predicate) Mean (SD)	Mean Difference (SD)	95% LOA	95% CI Lower LOA	95% CI Upper LOA
All Subjects							
Center (µm)	134	276.097 (35.3863)	265.068 (34.8798)	11.029 (5.5101)	(0.131, 21.928)	(-1.500, 1.761)	(20.297, 23.559)
Inner Temporal (µm)	134	320.440 (23.3739)	302.664 (22.2852)	17.776 (5.7303)	(6.442, 29.110)	(4.746, 8.138)	(27.415, 30.806)
Inner Superior (µm)	134	335.239 (23.7142)	314.455 (23.2685)	20.784 (5.5608)	(9.784, 31.783)	(8.139, 11.430)	(30.137, 33.428)
Inner Nasal (µm)	134	338.187 (21.0988)	317.963 (20.9016)	20.224 (5.7356)	(8.879, 31.569)	(7.182, 10.577)	(29.871, 33.266)
Inner Inferior (µm)	134	330.164 (21.5906)	309.761 (20.7669)	20.403 (6.0364)	(8.463, 32.343)	(6.677, 10.250)	(30.556, 34.129)
Outer Temporal (µm)	134	278.836 (18.6641)	269.007 (18.5478)	9.828 (5.7210)	(-1.488, 21.144)	(-3.181, 0.206)	(19.451, 22.837)
Outer Superior (µm)	134	291.582 (20.5746)	280.769 (21.3256)	10.813 (5.8876)	(-0.832, 22.459)	(-2.575, 0.910)	(20.716, 24.201)
Outer Nasal (µm)	134	304.515 (19.7799)	293.090 (20.2820)	11.425 (6.1551)	(-0.749, 23.600)	(-2.571, 1.072)	(21.778, 25.422)
Outer Inferior (µm)	134	281.381 (18.9728)	268.590 (19.1473)	12.791 (6.5328)	(-0.131, 25.713)	(-2.064, 1.803)	(23.779, 27.646)
Normal							
Center (µm)	45	272.467 (17.1538)	261.808 (17.2769)	10.658 (4.3789)	(1.833, 19.483)	(-0.445, 4.112)	(17.205, 21.762)
Inner Temporal (µm)	45	327.800 (12.4419)	308.600 (12.7304)	19.200 (6.4194)	(6.262, 32.138)	(2.922, 9.603)	(28.797, 35.478)
Inner Superior (µm)	45	343.489 (13.5824)	320.600 (13.3355)	22.889 (6.0386)	(10.719, 35.059)	(7.577, 13.861)	(31.917, 38.201)
Inner Nasal (µm)	45	344.200 (14.7980)	322.289 (14.6778)	21.911 (6.0521)	(9.714, 34.108)	(6.565, 12.863)	(30.959, 37.258)
Inner Inferior (µm)	45	337.711 (13.6509)	315.444 (12.9554)	22.267 (4.7645)	(12.665, 31.869)	(10.185, 15.144)	(29.390, 34.348)

Outer Temporal (µm)	45	286.622 (13.3387)	276.356 (12.7888)	10.267 (6.5796)	(-2.994, 23.527)	(-6.417, 0.430)	(20.103, 26.951)
Outer Superior (µm)	45	300.889 (14.7882)	289.578 (14.8989)	11.311 (5.4306)	(0.366, 22.256)	(-2.460, 3.192)	(19.430, 25.082)
Outer Nasal (µm)	45	313.156 (18.5079)	300.422 (16.7434)	12.733 (6.0317)	(0.577, 24.889)	(-2.562, 3.716)	(21.751, 28.028)
Outer Inferior (µm)	45	289.622 (15.3790)	275.778 (14.7030)	13.844 (5.5757)	(2.607, 25.082)	(-0.294, 5.509)	(22.180, 27.983)
Glaucoma							
Center (µm)	43	269.977 (17.4881)	258.562 (17.5655)	11.415 (4.8615)	(1.604, 21.226)	(-0.988, 4.195)	(18.634, 23.817)
Inner Temporal (µm)	43	311.907 (15.1104)	294.860 (14.4149)	17.047 (6.2104)	(4.513, 29.580)	(1.203, 7.824)	(26.269, 32.890)
Inner Superior (µm)	43	327.628 (15.5395)	307.000 (14.2812)	20.628 (5.8879)	(8.746, 32.510)	(5.607, 11.884)	(29.372, 35.649)
Inner Nasal (µm)	43	331.977 (14.4214)	312.256 (13.6784)	19.721 (6.1965)	(7.216, 32.226)	(3.913, 10.519)	(28.923, 35.529)
Inner Inferior (µm)	43	319.721 (17.5232)	300.558 (17.6302)	19.163 (7.3870)	(4.255, 34.070)	(0.318, 8.193)	(30.133, 38.008)
Outer Temporal (µm)	43	269.930 (15.4325)	260.302 (15.4805)	9.628 (5.3275)	(-1.123, 20.379)	(-3.963, 1.716)	(17.539, 23.219)
Outer Superior (µm)	43	282.140 (17.5819)	271.372 (16.5946)	10.767 (6.2786)	(-1.903, 23.438)	(-5.250, 1.444)	(20.091, 26.785)
Outer Nasal (µm)	43	296.837 (16.4403)	285.814 (16.0182)	11.023 (5.8614)	(-0.806, 22.852)	(-3.930, 2.319)	(19.728, 25.977)
Outer Inferior (µm)	43	270.349 (19.8265)	257.767 (17.6444)	12.581 (6.3555)	(-0.244, 25.407)	(-3.632, 3.143)	(22.019, 28.795)
Retinal Disease							
Center (µm)	46	285.370 (54.6892)	274.337 (53.6377)	11.032 (6.9749)	(-3.016, 25.080)	(-6.603, 0.572)	(21.493, 28.668)
Inner Temporal (µm)	46	321.217 (33.5545)	304.152 (31.9332)	17.065 (4.2079)	(8.590, 25.540)	(6.426, 10.754)	(23.376, 27.705)
Inner Superior (µm)	46	334.283 (33.6450)	315.413 (33.8254)	18.870 (3.8965)	(11.022, 26.717)	(9.017, 13.026)	(24.713, 28.722)
Inner Nasal (µm)	46	338.109 (28.8869)	319.065 (29.2380)	19.043 (4.5896)	(9.799, 28.287)	(7.439, 12.160)	(25.927, 30.648)
Inner Inferior (µm)	46	332.543 (27.2394)	312.804 (26.4143)	19.739 (5.4014)	(8.860, 30.618)	(6.082, 11.638)	(27.840, 33.396)
Outer Temporal (µm)	46	279.543 (22.2797)	269.957 (22.4914)	9.587 (5.2560)	(-0.999, 20.173)	(-3.703, 1.704)	(17.470, 22.877)
Outer Superior (µm)	46	291.304 (24.0184)	280.935 (26.6094)	10.370 (6.0309)	(-1.777, 22.516)	(-4.879, 1.325)	(19.414, 25.618)
Outer Nasal (µm)	46	303.239 (20.8925)	292.717 (24.4483)	10.522 (6.4524)	(-2.474, 23.517)	(-5.793, 0.845)	(20.199, 26.836)
Outer Inferior (µm)	46	283.630 (16.6244)	271.674 (20.2068)	11.957 (7.4951)	(-3.139, 27.052)	(-6.994, 0.716)	(23.197, 30.907)

Abbreviations: CI = Confidence Interval; ILM-RPE/BM = Inner Limiting Membrane-Retinal Pigment Epithelium/Bruch's Membrane; LOA = Limits of Agreement; SD = Standard Deviation; SQRT = Square Root.

Table 4: Summary of Limits of Agreement for All Configurations - Retinal Nerve Fiber Layer (RNFL) Thickness- Nidek (Test) Mirante Disc Map (Tracing HD OFF) and Optovue (Predicate) Avanti ONH with 3D Disc Disc Map – RNFL Thickness Analysis

Subject Population Comparable Parameter	N	Nidek Mirante (Test) Mean (SD)	Optovue Avanti (Predicate) Mean (SD)	Mean Difference (SD)	95% LOA	95% CI Lower LOA	95% CI Upper LOA
All Subjects							
Whole Chart (µm)	88	97.000 (16.3412)	88.596 (15.3816)	8.404 (4.6438)	(-0.826, 17.634)	(-2.531, 0.878)	(15.929, 19.338)
S/I Inferior (µm)	88	95.420 (17.5255)	86.719 (16.3613)	8.702 (6.3040)	(-3.828, 21.232)	(-6.142, -1.515)	(18.918, 23.545)
S/I Superior (µm)	88	98.511 (17.3411)	90.509 (15.4476)	8.003 (6.3740)	(-4.666, 20.672)	(-7.005, -2.327)	(18.333, 23.011)
TSNIT Temporal (µm)	88	67.102 (10.4980)	68.451 (11.3161)	-1.349 (9.6563)	(-20.542, 17.844)	(-24.086, -16.998)	(14.300, 21.388)
TSNIT Superior (µm)	88	115.000 (25.1935)	106.088 (19.4355)	8.912 (9.8988)	(-10.763, 28.587)	(-14.396, -7.131)	(24.954, 32.219)
TSNIT Nasal (µm)	88	84.102 (14.5563)	71.781 (12.9573)	12.321 (8.2437)	(-4.064, 28.706)	(-7.090, -1.039)	(25.681, 31.732)
TSNIT Inferior (µm)	88	121.682 (30.4025)	108.065 (24.8988)	13.616 (9.2922)	(-4.853, 32.086)	(-8.263, -1.443)	(28.676, 35.496)
Normal							
Whole Chart (µm)	45	107.200 (10.6571)	97.967 (9.7912)	9.233 (4.3936)	(0.378, 18.088)	(-1.908, 2.664)	(15.801, 20.374)
S/I Inferior (µm)	45	106.022 (12.1271)	96.297 (10.9840)	9.725 (5.3925)	(-1.143, 20.593)	(-3.949, 1.663)	(17.787, 23.399)
S/I Superior (µm)	45	108.267 (10.8007)	99.712 (9.4247)	8.554 (5.5885)	(-2.709, 19.817)	(-5.617, 0.200)	(16.909, 22.725)
TSNIT Temporal (µm)	45	68.356 (8.4803)	72.871 (8.0139)	-4.515 (8.1383)	(-20.917, 11.887)	(-25.152, -16.682)	(7.652, 16.121)
TSNIT Superior (µm)	45	129.178 (16.0981)	117.415 (11.5151)	11.762 (8.8701)	(-6.114, 29.639)	(-10.730, -1.498)	(25.023, 34.255)
TSNIT Nasal (µm)	45	90.844 (13.7807)	78.594 (11.3470)	12.250 (8.7671)	(-5.418, 29.919)	(-9.981, -0.856)	(25.357, 34.481)
TSNIT Inferior (µm)	45	140.200 (20.1433)	122.989 (15.5779)	17.211 (8.6067)	(-0.134, 34.557)	(-4.613, 4.344)	(30.078, 39.036)
Glaucoma							
Whole Chart (µm)	43	86.326 (14.3539)	78.790 (14.0397)	7.536 (4.7895)	(-2.130, 17.201)	(-4.683, 0.423)	(14.648, 19.754)
S/I Inferior (µm)	43	84.326 (15.3526)	76.695 (15.0647)	7.631 (7.0398)	(-6.576, 21.838)	(-10.329, -2.824)	(18.085, 25.590)
S/I Superior (µm)	43	88.302 (17.0888)	80.877 (14.6801)	7.426 (7.1255)	(-6.954, 21.806)	(-10.752, -3.156)	(18.007, 25.604)
TSNIT Temporal (µm)	43	65.791 (12.2271)	63.826 (12.4558)	1.965 (10.0886)	(-18.395, 22.324)	(-23.773, -13.017)	(16.947, 27.702)
TSNIT Superior (µm)	43	100.163 (24.5463)	94.235 (19.0323)	5.928 (10.1354)	(-14.526, 26.382)	(-19.929, -9.123)	(20.980, 31.785)
TSNIT Nasal (µm)	43	77.047 (11.8441)	64.652 (10.5414)	12.395 (7.7614)	(-3.268, 28.058)	(-7.405, 0.869)	(23.921, 32.195)
TSNIT Inferior (µm)	43	102.302 (27.1596)	92.448 (23.2730)	9.854 (8.5394)	(-7.379, 27.088)	(-11.931, -2.827)	(22.536, 31.639)

Abbreviations: CI = Confidence Interval; LOA = Limits of Agreement; SD = Standard Deviation; SQRT = Square Root; TSNIT = Temporal, Superior, Nasal, Inferior, Temporal.

Table 5: Summary of Limits of Agreement for All Configurations - Optic Disc Nidek (Test) Mirante Disc Map (Tracing HD OFF) and Optovue (Predicate) Avanti ONH with 3D Disc - Disc Map Optic Disc Analysis

Subject Population Comparable Parameter	N	Nidek Mirante (Test)	Optovue Avanti (Predicate) Mean (SD)	Mean Difference (SD)	95% LOA	95% CI Lower LOA	95% CI Upper LOA
All Subjects							
Horizontal C/D Ratio	88	0.599 (0.1805)	0.620 (0.2637)	-0.020 (0.1740)	(-0.366, 0.325)	(-0.430, -0.302)	(0.262, 0.389)
Vertical C/D Ratio	88	0.563 (0.1787)	0.575 (0.2650)	-0.012 (0.1745)	(-0.359, 0.335)	(-0.423, -0.295)	(0.271, 0.399)
Disc Area (mm^2)	88	2.130 (0.4577)	1.888 (0.3793)	0.241 (0.2494)	(-0.254, 0.737)	(-0.346, -0.163)	(0.646, 0.829)
Cup Area (mm^2)	88	0.799 (0.5287)	0.776 (0.5350)	0.023 (0.2373)	(-0.448, 0.495)	(-0.535, -0.361)	(0.408, 0.582)
Normal							
Horizontal C/D Ratio	45	0.511 (0.1189)	0.492 (0.2364)	0.018 (0.1977)	(-0.380, 0.417)	(-0.483, -0.277)	(0.314, 0.520)
Vertical C/D Ratio	45	0.467 (0.1252)	0.437 (0.2163)	0.030 (0.1944)	(-0.362, 0.422)	(-0.463, -0.261)	(0.321, 0.523)
Disc Area (mm^2)	45	2.135 (0.3282)	1.864 (0.3021)	0.271 (0.1995)	(-0.131, 0.673)	(-0.235, -0.027)	(0.569, 0.777)
Cup Area (mm^2)	45	0.541 (0.2754)	0.485 (0.3345)	0.055 (0.2236)	(-0.395, 0.506)	(-0.512, -0.279)	(0.390, 0.622)
Glaucoma							
Horizontal C/D Ratio	43	0.692 (0.1887)	0.753 (0.2237)	-0.061 (0.1358)	(-0.335, 0.213)	(-0.407, -0.263)	(0.141, 0.285)
Vertical C/D Ratio	43	0.663 (0.1721)	0.719 (0.2339)	-0.056 (0.1401)	(-0.339, 0.226)	(-0.414, -0.264)	(0.152, 0.301)
Disc Area (mm^2)	43	2.124 (0.5667)	1.914 (0.4484)	0.210 (0.2919)	(-0.379, 0.800)	(-0.534, -0.223)	(0.644, 0.955)
Cup Area (mm^2)	43	1.070 (0.5939)	1.080 (0.5388)	-0.010 (0.2491)	(-0.513, 0.492)	(-0.646, -0.380)	(0.360, 0.625)

Abbreviations: C/D = Cup-to-Disc; CI = Confidence Interval; LOA = Limits of Agreement; ONH = Optic Nerve Head; SD = Standard Deviation; SQRT = Square Root

Table 6: Summary of Limits of Agreement for All Configurations - Central Corneal Thickness (CCT) Nidek (Test) Mirante Cornea Radial and Optovue (Predicate) Avanti Pachymetry - Cornea Radial CCT Analysis

Subject Population Comparable Parameter	N	Nidek Mirante (Test) Mean (SD)	Optovue Avanti (Predicate) Mean (SD)	Mean Difference (SD)	95% LOA	95% CI Lower LOA	95% CI Upper LOA
All Subjects							
CCT (µm)	64	541.844 (36.7200)	525.828 (38.9650)	16.016 (5.5677)	(4.889, 27.142)	(2.480, 7.298)	(24.733, 29.551)
Normal							
CCT (µm)	45	543.867 (26.5515)	527.356 (26.1466)	16.511 (3.9117)	(8.628, 24.395)	(6.592, 10.663)	(22.359, 26.430)
Corneal Disease							
CCT (µm)	19	537.053 (54.4196)	522.211 (60.1928)	14.842 (8.3084)	(-2.613, 32.297)	(-9.549, 4.323)	(25.361, 39.233)

Abbreviations: CCT=Central Corneal Thickness; CI = Confidence Interval; LOA = Limits of Agreement; SD = Standard Deviation.

Precision Analyses: Mirante / Avanti Analyses:

For the precision analyses between Mirante and Avanti, the Mirante device met precision performance goals, with acceptable variation among all parameters and each group (Normal, Glaucoma, and Retinal Disease) for [ILM-RPE/BM] Thickness for repeatability.

For Disc Map RNFL Thickness, overall the Mirante device met most precision performance goals, with acceptable variation among all parameters in the Normal population, and among all but one TSNIT Nasal and one TSNIT Temporal parameter in the Glaucoma population for repeatability, which did not meet performance goals only slightly.

For Disc Map Optic Disc, overall the Mirante device met most precision performance goals, with acceptable variation among all parameters for repeatability in the Normal and Glaucoma populations, with the exception of cup area in both populations, which did not meet performance goals only slightly.

For Cornea Radial CCT, the Mirante device met precision performance goals, with acceptable variation among all

parameters and all populations for repeatability.

Table 7: Summary of Repeatability and Reproducibility for [ILM-RPE/BM] Thickness Nidek (Test) Mirante Macula Map (9 x 9 mm Tracing HD OFF) and Optovue (Predicate) Avanti Retina Map - [ILM-RPE/BM] Thickness Analysis Set

			Repeatability			Reproducibility		
Device Comparable Parameter	**N**	**Overall Mean**	**%CV**	**%CV Lower 95% CI**	**%CV Upper 95% CI**	**%CV**	**%CV Lower 95% CI**	**%CV Upper 95% CI**
All Subjects								
Nidek Mirante								
Center (µm)	128	276.093	1.083%	1.031%	1.140%	1.263%	1.211%	1.320%
Inner Temporal (µm)	128	320.837	0.615%	0.586%	0.647%	0.805%	0.772%	0.842%
Inner Superior (µm)	128	335.394	0.620%	0.590%	0.653%	0.831%	0.797%	0.869%
Inner Nasal (µm)	128	337.909	0.513%	0.488%	0.539%	0.718%	0.689%	0.751%
Inner Inferior (µm)	128	330.687	0.672%	0.640%	0.708%	0.882%	0.845%	0.922%
Outer Temporal (µm)	128	278.721	0.847%	0.807%	0.892%	1.047%	1.004%	1.095%
Outer Superior (µm)	128	292.070	0.745%	0.710%	0.785%	0.920%	0.882%	0.961%
Outer Nasal (µm)	128	304.707	0.515%	0.490%	0.542%	0.702%	0.673%	0.734%
Outer Inferior (µm)	128	280.759	0.985%	0.938%	1.037%	1.374%	1.317%	1.436%
Optovue Avanti								
Center (µm)	128	265.248	0.807%	0.768%	0.849%	0.967%	0.927%	1.011%
Inner Temporal (µm)	128	303.230	0.959%	0.913%	1.009%	1.190%	1.141%	1.244%
Inner Superior (µm)	128	315.142	0.900%	0.857%	0.947%	1.122%	1.076%	1.173%
Inner Nasal (µm)	128	318.527	0.955%	0.910%	1.005%	1.127%	1.080%	1.178%
Inner Inferior (µm)	128	310.091	0.893%	0.850%	0.940%	1.124%	1.077%	1.175%

			Repeatability			Reproducibility		
Device Comparable Parameter	**N**	**Overall Mean**	**%CV**	**%CV Lower 95% CI**	**%CV Upper 95% CI**	**%CV**	**%CV Lower 95% CI**	**%CV Upper 95% CI**
Outer Temporal (µm)	128	269.219	0.881%	0.839%	0.928%	1.106%	1.060%	1.156%
Outer Superior (µm)	128	281.515	0.833%	0.793%	0.877%	1.115%	1.068%	1.165%
Outer Nasal (µm)	128	293.518	0.729%	0.694%	0.767%	0.880%	0.844%	0.920%
Outer Inferior (µm)	128	268.654	0.838%	0.798%	0.882%	1.046%	1.003%	1.094%
Normal								
Nidek Mirante								
Center (µm)	44	271.242	1.034%	0.953%	1.130%	1.284%	1.196%	1.386%
Inner Temporal (µm)	44	327.341	0.425%	0.392%	0.465%	0.620%	0.577%	0.670%
Inner Superior (µm)	44	342.879	0.606%	0.558%	0.662%	0.797%	0.742%	0.860%
Inner Nasal (µm)	44	343.891	0.465%	0.428%	0.508%	0.664%	0.619%	0.717%
Inner Inferior (µm)	44	337.672	0.502%	0.463%	0.549%	0.733%	0.682%	0.791%
Outer Temporal (µm)	44	286.492	0.764%	0.704%	0.835%	0.969%	0.902%	1.046%
Outer Superior (µm)	44	301.556	0.682%	0.628%	0.745%	0.834%	0.777%	0.901%

Outer Nasal (µm)	44	313.465	0.415%	0.382%	0.454%	0.628%	0.585%	0.678%
Outer Inferior (µm)	44	288.927	0.865%	0.797%	0.945%	1.350%	1.257%	1.457%
Optovue Avanti								
Center (µm)	44	260.974	0.669%	0.617%	0.731%	0.951%	0.885%	1.027%
Inner Temporal (µm)	44	308.816	1.023%	0.943%	1.119%	1.420%	1.322%	1.533%
Inner Superior (µm)	44	321.197	0.999%	0.921%	1.092%	1.294%	1.205%	1.398%
Inner Nasal (µm)	44	322.412	1.008%	0.929%	1.102%	1.270%	1.183%	1.371%
Inner Inferior (µm)	44	315.159	0.906%	0.835%	0.991%	1.321%	1.230%	1.426%
Outer Temporal (µm)	44	276.361	0.883%	0.814%	0.966%	1.196%	1.114%	1.291%
Outer Superior (µm)	44	290.141	0.778%	0.717%	0.851%	1.035%	0.964%	1.118%
Outer Nasal (µm)	44	300.821	0.761%	0.701%	0.832%	0.959%	0.893%	1.035%
Outer Inferior (µm)	44	275.573	0.763%	0.704%	0.835%	1.080%	1.006%	1.166%
Glaucoma								
Nidek Mirante								
Center (µm)	40	269.642	1.031%	0.946%	1.132%	1.178%	1.093%	1.277%
Inner Temporal (µm)	40	312.589	0.433%	0.397%	0.475%	0.706%	0.655%	0.765%
Inner Superior (µm)	40	327.497	0.531%	0.487%	0.583%	0.815%	0.757%	0.884%
Inner Nasal (µm)	40	331.311	0.441%	0.405%	0.485%	0.680%	0.632%	0.738%
Inner Inferior (µm)	40	320.528	0.678%	0.623%	0.745%	0.899%	0.834%	0.974%
Outer Temporal (µm)	40	269.889	0.786%	0.722%	0.863%	1.014%	0.941%	1.099%
Outer Superior (µm)	40	282.653	0.784%	0.720%	0.861%	1.042%	0.967%	1.129%
Outer Nasal (µm)	40	296.861	0.528%	0.484%	0.579%	0.672%	0.624%	0.729%
Outer Inferior (µm)	40	269.669	1.012%	0.929%	1.111%	1.366%	1.268%	1.481%
Optovue Avanti								

			Repeatability			**Reproducibility**		
Device Comparable Parameter	**N**	**Overall Mean**	**%CV**	**%CV Lower 95% CI**	**%CV Upper 95% CI**	**%CV**	**%CV Lower 95% CI**	**%CV Upper 95% CI**
Center (µm)	40	258.359	0.707%	0.649%	0.776%	0.829%	0.769%	0.898%
Inner Temporal (µm)	40	295.250	0.899%	0.826%	0.988%	1.073%	0.996%	1.163%
Inner Superior (µm)	40	307.531	0.839%	0.770%	0.921%	1.008%	0.935%	1.092%
Inner Nasal (µm)	40	312.192	0.809%	0.743%	0.889%	0.962%	0.893%	1.043%
Inner Inferior (µm)	40	300.550	0.858%	0.788%	0.942%	0.987%	0.916%	1.070%
Outer Temporal (µm)	40	260.625	0.776%	0.712%	0.852%	0.932%	0.865%	1.010%
Outer Superior (µm)	40	272.317	0.773%	0.710%	0.849%	0.921%	0.855%	0.998%
Outer Nasal (µm)	40	285.511	0.631%	0.580%	0.693%	0.789%	0.732%	0.855%
Outer Inferior (µm)	40	257.772	0.689%	0.633%	0.757%	0.832%	0.772%	0.902%
Retinal Disease								
Nidek Mirante								
Center (µm)	44	286.808	1.163%	1.072%	1.271%	1.309%	1.219%	1.413%

Inner Temporal (µm)	44	321.831	0.863%	0.796%	0.944%	1.025%	0.954%	1.107%
Inner Superior (µm)	44	335.088	0.701%	0.646%	0.766%	0.879%	0.818%	0.949%
Inner Nasal (µm)	44	337.924	0.608%	0.561%	0.665%	0.800%	0.745%	0.864%
Inner Inferior (µm)	44	332.937	0.806%	0.743%	0.881%	0.999%	0.931%	1.079%
Outer Temporal (µm)	44	278.980	0.971%	0.895%	1.062%	1.149%	1.070%	1.241%
Outer Superior (µm)	44	291.146	0.776%	0.715%	0.848%	0.895%	0.834%	0.966%
Outer Nasal (µm)	44	303.081	0.593%	0.546%	0.648%	0.795%	0.740%	0.858%
Outer Inferior (µm)	44	282.672	1.075%	0.990%	1.175%	1.402%	1.306%	1.514%
Optovue Avanti								
Center (µm)	44	275.784	0.976%	0.899%	1.067%	1.077%	1.003%	1.163%
Inner Temporal (µm)	44	304.899	0.939%	0.865%	1.027%	1.013%	0.944%	1.094%
Inner Superior (µm)	44	316.008	0.839%	0.773%	0.918%	1.019%	0.949%	1.100%
Inner Nasal (µm)	44	320.402	1.014%	0.934%	1.108%	1.104%	1.028%	1.192%
Inner Inferior (µm)	44	313.697	0.907%	0.836%	0.991%	1.009%	0.939%	1.089%
Outer Temporal (µm)	44	269.889	0.959%	0.884%	1.048%	1.141%	1.063%	1.232%
Outer Superior (µm)	44	281.250	0.932%	0.858%	1.018%	1.326%	1.235%	1.432%
Outer Nasal (µm)	44	293.495	0.772%	0.711%	0.844%	0.868%	0.808%	0.937%
Outer Inferior (µm)	44	271.626	1.005%	0.926%	1.099%	1.160%	1.081%	1.253%

Abbreviations: CI = Confidence Interval; CV = Coefficient of Variation; ILM-RPE/BM = Inner Limiting Membrane-Retinal Pigment Epithelium/Bruch's Membrane; REML = Restricted Maximum Likelihood Method; SD = Standard Deviation.

Table 8: Summary of Repeatability and Reproducibility for Retinal Nerve Fiber Layer (RNFL) Thickness Nidek (Test) Mirante Disc Map (Tracing HD OFF) and Optovue (Predicate) Avanti ONH with 3D Disc - Disc Map RNFL Thickness Analysis Set

			Repeatability			Reproducibility		
Device Comparable Parameter	**N**	**Overall Mean**	**%CV**	**%CV Lower 95% CI**	**%CV Upper 95% CI**	**%CV**	**%CV Lower 95% CI**	**%CV Upper 95% CI**
All Subjects								
Nidek Mirante								
TSNIT Inferior (µm)	74	124.710	4.715%	4.424%	5.048%	4.934%	4.668%	5.233%
TSNIT Nasal (µm)	74	84.308	7.198%	6.753%	7.707%	7.422%	7.021%	7.873%
TSNIT Superior (µm)	74	117.785	4.891%	4.589%	5.236%	5.869%	5.552%	6.225%
TSNIT Temporal (µm)	74	66.875	6.084%	5.708%	6.513%	6.340%	5.998%	6.725%
Whole Chart (µm)	74	98.416	2.812%	2.638%	3.010%	3.097%	2.930%	3.285%
S/I Inferior (µm)	74	96.655	4.629%	4.343%	4.956%	4.854%	4.593%	5.148%
S/I Superior (µm)	74	100.164	4.577%	4.294%	4.899%	5.165%	4.886%	5.478%
Optovue Avanti								
TSNIT Inferior (µm)	74	110.853	2.835%	2.660%	3.035%	3.042%	2.878%	3.226%
TSNIT Nasal (µm)	74	72.811	3.270%	3.068%	3.500%	3.566%	3.374%	3.782%
TSNIT Superior (µm)	74	107.791	2.582%	2.423%	2.764%	2.933%	2.775%	3.110%
TSNIT Temporal (µm)	74	68.668	3.926%	3.683%	4.203%	4.152%	3.928%	4.403%
Whole Chart (µm)	74	90.031	1.485%	1.394%	1.590%	1.736%	1.642%	1.841%
S/I Inferior (µm)	74	88.114	2.179%	2.045%	2.332%	2.318%	2.193%	2.458%
S/I Superior (µm)	74	91.942	1.819%	1.707%	1.947%	2.255%	2.134%	2.391%
Normal								
Nidek Mirante								
TSNIT Inferior (µm)	40	139.464	3.813%	3.500%	4.188%	4.143%	3.845%	4.491%
TSNIT Nasal (µm)	40	88.853	6.730%	6.177%	7.394%	6.870%	6.374%	7.449%
TSNIT Superior (µm)	40	130.361	3.708%	3.404%	4.073%	5.070%	4.705%	5.497%
TSNIT Temporal (µm)	40	68.953	4.514%	4.143%	4.958%	4.927%	4.572%	5.341%
Whole Chart (µm)	40	106.894	2.268%	2.081%	2.490%	2.676%	2.484%	2.901%
S/I Inferior (µm)	40	104.989	3.950%	3.625%	4.338%	4.221%	3.917%	4.576%
S/I Superior (µm)	40	108.806	3.550%	3.258%	3.899%	4.170%	3.870%	4.520%
Optovue Avanti								
TSNIT Inferior (µm)	40	123.259	2.047%	1.879%	2.248%	2.459%	2.282%	2.666%
TSNIT Nasal (µm)	40	78.506	2.937%	2.696%	3.226%	3.221%	2.990%	3.492%
TSNIT Superior (µm)	40	118.005	2.422%	2.223%	2.660%	2.674%	2.482%	2.899%
TSNIT Temporal (µm)	40	73.065	3.531%	3.241%	3.878%	3.788%	3.516%	4.107%
Whole Chart (µm)	40	98.209	1.271%	1.167%	1.396%	1.580%	1.467%	1.713%
S/I Inferior (µm)	40	96.199	1.657%	1.521%	1.820%	1.918%	1.780%	2.079%
S/I Superior (µm)	40	100.213	1.617%	1.484%	1.776%	1.993%	1.850%	2.161%

Glaucoma

			Repeatability			Reproducibility		
Device Comparable Parameter	**N**	**Overall Mean**	**%CV**	**%CV Lower 95% CI**	**%CV Upper 95% CI**	**%CV**	**%CV Lower 95% CI**	**%CV Upper 95% CI**
Nidek Mirante								
TSNIT Inferior (µm)	34	107.353	6.015%	5.482%	6.663%	6.125%	5.649%	6.689%
TSNIT Nasal (µm)	34	78.961	7.814%	7.121%	8.657%	8.149%	7.514%	8.901%
TSNIT Superior (µm)	34	102.990	6.495%	5.920%	7.195%	7.043%	6.496%	7.692%
TSNIT Temporal (µm)	34	64.431	7.703%	7.020%	8.534%	7.846%	7.235%	8.570%
Whole Chart (µm)	34	88.441	3.531%	3.219%	3.911%	3.680%	3.395%	4.018%
S/I Inferior (µm)	34	86.850	5.563%	5.071%	6.162%	5.735%	5.290%	6.263%
S/I Superior (µm)	34	89.997	5.900%	5.377%	6.535%	6.482%	5.978%	7.079%
Optovue Avanti								
TSNIT Inferior (µm)	34	96.258	3.881%	3.537%	4.298%	3.881%	3.580%	4.237%
TSNIT Nasal (µm)	34	66.111	3.731%	3.401%	4.132%	4.046%	3.732%	4.417%
TSNIT Superior (µm)	34	95.774	2.812%	2.564%	3.114%	3.307%	3.051%	3.611%
TSNIT Temporal (µm)	34	63.494	4.451%	4.057%	4.930%	4.640%	4.280%	5.067%
Whole Chart (µm)	34	80.409	1.785%	1.627%	1.976%	1.959%	1.807%	2.139%
S/I Inferior (µm)	34	78.602	2.855%	2.602%	3.161%	2.865%	2.643%	3.128%
S/I Superior (µm)	34	82.211	2.106%	1.920%	2.332%	2.626%	2.423%	2.868%

Abbreviations: CI = Confidence Interval; CV = Coefficient of Variation; REML = Restricted Maximum Likelihood Method; RNFL = Retinal Nerve Fiber Layer; SD = Standard Deviation; S/I = Superior/Inferior; TSNIT = Temporal, Superior, Nasal, Inferior, Temporal.

Table 9: Summary of Repeatability and Reproducibility for Optic Disc Nidek (Test) Mirante Disc Map (Tracing HD OFF) and Optovue (Predicate) Avanti ONH with 3D Disc - Disc Map Optic Disc Analysis Set

			Repeatability			Reproducibility		
Device Comparable Parameter	**N**	**Overall Mean**	**%CV**	**%CV Lower 95% CI**	**%CV Upper 95% CI**	**%CV**	**%CV Lower 95% CI**	**%CV Upper 95% CI**
All Subjects								
Nidek Mirante								
Horizontal C/D Ratio	73	0.598	8.021%	7.521%	8.592%	8.772%	8.294%	9.310%
Vertical C/D Ratio	73	0.557	6.619%	6.207%	7.090%	7.574%	7.161%	8.037%
Disc Area (mm^2)	73	2.132	6.710%	6.292%	7.187%	6.806%	6.435%	7.222%
Cup Area (mm^2)	73	0.763	11.799%	11.061%	12.645%	13.686%	12.932%	14.533%
Optovue Avanti								
Horizontal C/D Ratio	73	0.605	6.310%	5.917%	6.758%	6.522%	6.168%	6.921%
Vertical C/D Ratio	73	0.562	7.300%	6.845%	7.820%	7.903%	7.472%	8.387%
Disc Area (mm^2)	73	1.890	4.559%	4.275%	4.882%	4.916%	4.649%	5.216%
Cup Area (mm^2)	73	0.734	6.984%	6.550%	7.481%	7.328%	6.929%	7.777%
Normal								
Nidek Mirante								
Horizontal C/D Ratio	40	0.529	9.380%	8.606%	10.307%	10.055%	9.326%	10.907%
Vertical C/D Ratio	40	0.482	7.394%	6.785%	8.123%	8.564%	7.945%	9.288%

			Repeatability			Reproducibility		
Device Comparable Parameter	**N**	**Overall Mean**	**%CV**	**%CV Lower 95% CI**	**%CV Upper 95% CI**	**%CV**	**%CV Lower 95% CI**	**%CV Upper 95% CI**
Disc Area (mm^2)	40	2.144	5.892%	5.408%	6.472%	6.156%	5.713%	6.675%
Cup Area (mm^2)	40	0.574	14.148%	12.974%	15.559%	16.255%	15.063%	17.655%
Optovue Avanti								
Horizontal C/D Ratio	40	0.501	8.768%	8.046%	9.635%	9.032%	8.379%	9.796%
Vertical C/D Ratio	40	0.442	9.868%	9.054%	10.845%	10.541%	9.777%	11.436%
Disc Area (mm^2)	40	1.880	4.329%	3.974%	4.755%	4.787%	4.443%	5.190%
Cup Area (mm^2)	40	0.503	8.177%	7.504%	8.984%	8.578%	7.958%	9.304%
Glaucoma								
Nidek Mirante								
Horizontal C/D Ratio	33	0.680	6.725%	6.121%	7.462%	7.560%	6.963%	8.268%
Vertical C/D Ratio	33	0.647	5.912%	5.382%	6.560%	6.676%	6.150%	7.301%
Disc Area (mm^2)	33	2.117	7.553%	6.874%	8.381%	7.553%	6.957%	8.261%
Cup Area (mm^2)	33	0.992	10.047%	9.142%	11.152%	11.741%	10.809%	12.850%
Optovue Avanti								
Horizontal C/D Ratio	33	0.732	4.074%	3.709%	4.520%	4.251%	3.916%	4.648%
Vertical C/D Ratio	33	0.707	5.319%	4.842%	5.901%	5.881%	5.418%	6.432%
Disc Area (mm^2)	33	1.902	4.816%	4.384%	5.343%	5.064%	4.666%	5.537%
Cup Area (mm^2)	33	1.014	6.050%	5.507%	6.712%	6.348%	5.848%	6.943%

Abbreviations: CI = Confidence Interval; CV = Coefficient of Variation; REML = Restricted Maximum Likelihood Method; RNFL = Retinal Nerve Fiber Layer; SD = Standard Deviation; S/I = Superior/Inferior; TSNIT = Temporal, Superior, Nasal, Inferior, Temporal.

Table 10: Summary of Repeatability and Reproducibility for Central Corneal Thickness (CCT) Nidek (Test) Mirante Cornea Radial and Optovue (Predicate) Avanti Pachymetry - Cornea Radial CCT Analysis Set

			Repeatability			Reproducibility		
Device Comparable Parameter	**N**	**Overall Mean**	**%CV**	**%CV Lower 95% CI**	**%CV Upper 95% CI**	**%CV**	**%CV Lower 95% CI**	**%CV Upper 95% CI**
All Subjects								
Nidek Mirante								
Central Corneal Thickness (µm)	60	542.628	0.656%	0.612%	0.708%	0.799%	0.752%	0.853%
Optovue Avanti								
Central Corneal Thickness (µm)	60	526.661	0.534%	0.498%	0.576%	0.769%	0.723%	0.821%
Normal								
Nidek Mirante								
Central Corneal Thickness (µm)	42	543.217	0.535%	0.492%	0.586%	0.709%	0.659%	0.767%
Optovue Avanti								
Central Corneal Thickness (µm)	42	526.571	0.327%	0.301%	0.359%	0.470%	0.437%	0.509%
Corneal Disease								
Nidek Mirante								
Central Corneal Thickness (µm)	18	541.253	0.878%	0.775%	1.013%	0.980%	0.879%	1.108%
Optovue Avanti								
Central Corneal Thickness (µm)	18	526.870	0.837%	0.739%	0.965%	1.206%	1.081%	1.363%

Abbreviations: CCT=Central Corneal Thickness; CI = Confidence Interval; CV = Coefficient of Variation; REML = Restricted Maximum Likelihood Method; SD = Standard Deviation.

Precision Analyses: Mirante Only Analyses:

For the Mirante only precision analyses, both Mirante settings met precision performance goals, with acceptable variation among all parameters and each population for repeatability for Macula Size and Macula Trace. For Disc Trace RNFL Thickness and Disc Trace Optic Disc, both Mirante settings did not meet performance goals for some parameters in the Normal and Glaucoma populations. For Mirante-only Cornea Radial CCT, both devices met the precision performance goals, with acceptable variation among all parameters and each population for repeatability.

Image Quality

Masked graders reviewing Anterior Chamber Angle (ACA) and SLO images were masked to the subject, device type, subject population, configuration order, device order and results from other graders. Graders viewed the images using a secure file sharing platform. The graders only viewed and graded a single image at a time.

Image quality was assessed based on clinical utility and overall quality for both Mirante and Avanti or P200DTx devices on different paired scan types. **Agreement of SLO Image Quality of Nidek Mirante and OPTOS P200DTx**

The first acceptable SLO image captured by the Mirante and corresponding OPTOS P200DTx were compared to assess image quality. The results from the 3 masked graders were documented.

Table 11: SLO Images Compared by Device

Mirante	P200DTx
Color	Color
B-FAF	FAF
G-FAF	FAF

For SLO Color Fundus analysis, Mirante provided better clinical utility and overall quality in comparison to P200DTx (1-Sided Wilcoxon Signed-Rank Test; $p<0.0001$) for the grader average in the All Subjects population as well as in the individual Normal ($p<0.0001$), Glaucoma ($p<0.0001$), and Retinal Disease (Clinical Utility $p<0.0001$; Overall quality $p = 0.0009$) group.

For SLO B-Fundus Autofluorescence (FAF) analysis, Mirante provided better clinical utility and overall quality in comparison to P200DTx (1-Sided Wilcoxon Signed-Rank Test; $p<0.0001$) for the grader average in the All Subjects population as well as in the individual Normal ($p<0.0001$), Glaucoma ($p<0.0001$), and Retinal Disease ($p = 0.0006$) group.

For SLO G-FAF analysis, Mirante provided better clinical utility and overall quality in comparison to P200DTx (1-Sided Wilcoxon Signed-Rank Test; $p<0.0001$) for the grader average in the All Subjects population as well as in the individual Normal ($p<0.0001$), Glaucoma ($p<0.0001$), and Retinal Disease ($p< 0.0001$) group.

Agreement of OCT ACA Image Quality of Nidek Mirante and Avanti

The first acceptable OCT ACA image captured by the Mirante and corresponding Angle line image captured by the Avanti were compared to assess image quality.

For ACA analysis, clinical utility and overall quality in comparison to Avanti were not statistically significant for any of the populations.

Safety Results:

No safety-related issues related to the study devices were identified. There was a total of one adverse event of

pinguecula in both eyes reported by one subject in the Normal population in this study, which was determined to be not related to the study device. The affected subject completed the study.

OCT/SLO Clinical Conclusion

In conclusion, agreement performance goals were met between Mirante and Avanti for [ILM-RPE/BM] Disc Map RNFL Thickness, and Optic Disc analysis for all parameters and each individual population. Mean differences between Mirante and Avanti scans (Mirante – Avanti) were higher for all populations for [ILM-RPE/BM] Thickness analysis and were higher for most parameters for Disc Map RNFL Thickness. For [ILM- RPE/BM] Thickness, Mirante is likely thicker by around 10-20 μm than Avanti due to the definition of lower line, where Mirante measures between RPE and BM while Avanti measure on RPE. Additionally, for the upper line, Mirante measure the upper line (vitreous side) of ILM whereas Avanti measure on ILM. For Disc Map – RFNL Thickness, Mirante is likely thicker (around 10 μm), with the exception of TSNIT Temporal, due to the difference of segmentation algorism of blood vessels area, especially large blood vessels, with Mirante measuring line underside of blood vessels and Avanti crossing blood vessels. The exception of TSNIT Temporal being similar for both devices is because large blood vessels do not run in the Temporal area anatomically.

For the precision analyses, the Mirante device met precision performance goals for all parameters and each individual population for [ILM-RPE/BM] Thickness and Cornea Radial CCT for repeatability. Overall, the Mirante device met most precision performance goals for all parameters in the Normal population, and most parameters in the Glaucoma population for repeatability for Disc Map RNFL Thickness. For Optic Disc, the Mirante device met performance goals for all but one parameter for both Normal and Glaucoma populations. For Mirante only precision analyses, the precision performance goals were met for all parameters and all populations for repeatability for macula size, macula trace, and Cornea Radial CCT.

Image quality analyses demonstrated that Mirante provided better clinical utility and overall quality in comparison to P200DTx for SLO Color Fundus, SLO B-FAF, and SLO G-FAF analyses respectively, for the grader average in the All Subjects and each individual population.

Additionally, no safety-related issues related to the study devices were identified.

Thus, the several agreement and precision qualities and the clinical utility and overall quality of image with the Mirante device demonstrate its benefit in a clinical practice setting.

Image Filing Software NAVIS-EX

NAVIS-EX Device Description

The device includes Image Filing Software NAVIS-EX which is a software system intended for use to store, manage, process, measure, analyze and display patient data and clinical information from computerized diagnostic instruments through networks. It is intended to work with compatible NIDEK ophthalmic devices.

NAVIS-EX is equipped with functions for image acquisition, image display, image drawing, image processing, image measurement, panorama image creation, stereo image observation, AF composite image creation, color composite image creation, viewer display of OCT image, and OCT image Follow-Up. (Depending on the image type, available functions are limited.) In addition, image data can be transferred by network or e-mail.

A network can be configured with multiple NAVIS-EX-installed computers, allowing access from the client computers for reference and editing.

The basic common functions that are provided by the NAVIS-EX software are listed in the table below.

Table 12: NAVIS-EX Common Functions

Function	Function Description
Network function	Adds and refers to data from multiple terminals configuring a network.
Image display function	Displays the images per patient.
Search function	Searches the captured data by patient information, date, and time period.
Zoom function	Enlarges and reduces the saved images.
Printing function	Prints the images or lists in a selected format. Exports and imports a print template.
E-mail sending function	Sends the saved images by e-mail.
Report function	Outputs a report of data containing the saved images and patient information to the specified destination.
External application activation function	Displays the saved images with an external application that can open JPEG and BMP files.
External system communication function	Acquires patient information from an external system, and outputs data to an external system.
Patient specification function	Registers patient information using the command line or file linkage from an external system. It also allows specification of the patient to be displayed.
DICOM communication	Communicates data and saves the images in accordance with the DICOM standard.
Ophthalmic photography device communication function	Imports the images and XML files from the connected device.
Import and export functions	Acquires and outputs specified NAVIS-EX data for data exchange.
Data encryption/decryption function	Encrypts patient information, exported data, and backup data, and decrypts the encrypted imported data and restored data.
New Function: B-scan Denoising software	Processes the B-scan OCT images acquired from NIDEK devices to create clear OCT images with noise removed.

There are additional functions available based on the type of image that are detailed in the Operators Manual. These are summarized in the following table.

Table 13: NAVIS-EX Functions based on type of image

○Functions depending on type of image

Availability of function differ depending on the type of image (capturing device).Availability of function differ depending on the type of image (capturing device).

		AFC-330/ DS-10/20	Mirante	RS-3000 Advance
Acquiring images	"3.5 Acquiring Images (AFC-330)" (page 67)	○	×	×
	"3.6 Acquiring Images (RS-3000 Advance)" (page 68)	×	×	○
	"3.8 Acquiring Images (Import)" (page 70)	×	○	×
	"3.8 Acquiring Images (Import)" (page 70)	○	○	○
Image reference	"4.1 Image List Screen" (page 137)	○	○	×
	"12 VIEWER DISPLAY OF OCT IMAGE" (page 337)	×	○*1	○
Printing image data	"4.4 Printing Image Data" (page 168)	○	○	○
Exporting image data	"4.5 Export" (page 178)	○	○	×
	"12.15 Exporting OCT Images" (page 425)	×	○*1	○
Sending image data by e-mail	"4.6 E-mail Sending Function" (page 182)	○	○	×
	"12.16 Sending OCT Images by E-mail" (page 428)	×	○*1	○
Drawing to image	"7 DRAWING FUNCTION" (page 239)	○	○*2	×
Processing images	"8 IMAGE PROCESSING" (page 269)	○	○*2	×
Measuring image distance and dimension	"9 IMAGE MEASUREMENT" (page 281)	○	○*2	×
Creating panorama composite images	"10 PANORAMA IMAGE FUNCTION" (page 295)	○	○*2	×
Stereo image creation and observation	"11 STEREO VIEWING" (page 331)	○	○*2	×
Follow-Up	"3.12 Fundus Image Follow-Up" (page 116)	○	×	×
	"13 OCT IMAGE Follow-Up" (page 433)	×	×	○

△: Only still images can be captured

*1: Mirante OCT image

*2: Mirante "Fundus SLO" image

Note

- SLO image capture data of the Mirante can be displayed while Mirante Viewer is active. To display that data on the NAVIS-EX viewer, the data needs to be registered to NAVIS-EX as a "Fundus SLO" image using Mirante Viewer.

Indications for Use

The Image Filing Software NAVIS-EX is a software system intended for use to store, manage, process, measure, analyze and display patient data and clinical information from computerized diagnostic instruments through networks. It is intended to work with compatible NIDEK ophthalmic devices.

Statement of Substantial Equivalence

Nidek believes that the Image Filing Software NAVIS -EX described in this notification and for use under the conditions of the proposed labeling is substantially equivalent to the legally marketed predicate device. This is Class II medical device Image Filing Software NAVIS -EX cleared in K181345.

Therefore, based on the same intended use and technological characteristics with substantial equivalence to the predicate devices confirmed with performance testing, the NAVIS-EX is technologically and functionally equivalent to the predicate device. The difference between the proposed device and the predicate device is not significant and do not raise new issues of safety or effectiveness of the device.

The Comparison Table of Technological Characteristics follows.

Table 14: Comparison Table of Technological Characteristics – NAVIS-EX

		Subject Device	Predicate Device	Discussion
Device Name		Image Filing Software NAVIS-EX	Image Filing Software NAVIS-EX	Same
Version		V1.11.0	V1.5.4	
510(k) Number			K181345	
Classification, Product Code		Class II NFJ	Class II NFJ	
Applicant		Nidek Co., Ltd.	Nidek Co., Ltd.	
Filing				
	Network function	Yes	Yes	Same
	Image display function	Yes	Yes	Same
	Search function (patient information, date, period)	Yes	Yes	Same
	Zoom function	Yes	Yes	Same
	3D display function (OCT image)	Yes	Yes	Same
	Printing function (single printing, multiple random layout printing, template)	Yes	Yes	Same
External I/F				Same
	E-mail function (sending image by e-mail)	Yes	Yes	Same
	Report function (report data output)	Yes	Yes	Same
	External application activation function (view the selected images from an external application)	Yes	Yes	Same
	Link function (patient information acquisition and data output)	Yes	Yes	Same
	Patient specification function (specify the patient from an external system)	Yes	Yes	Same
	DICOM	Yes	Yes	Same
Image acquisition				Same
	Link function	RS-3000 Advance Capture, Mirante Capture	RS-3000 Advance Capture	Added Mirante
	Import function	Yes	Yes	Same
	DCIM import function	Yes	Yes	Same
	Patient import/export function	Yes	Yes	Same
	Multiple patient import/export function	Yes	Yes	Same
	Patient export function specifying examination data	Yes	Yes	Same
Image processing				Same
	Effect function	Yes	Yes	Same
	Color correction function	Yes	Yes	Same
	Rotate/Mirror function	Yes	Yes	Same
	Resize function	Yes	Yes	Same

		Subject Device	Predicate Device	Discussion
Device Name		Image Filing Software NAVIS-EX	Image Filing Software NAVIS-EX	Same
	Measurement function	Yes	Yes	Same
	Filter processing	Yes	Yes	Same
	Simple image processing	Yes	Yes	Same
	Stereo function	Yes	Yes	Same
	Panorama function	Yes	Yes	Same
	Composite function	Yes	Yes	Same
	Drawing function	Yes	Yes	Same
	3D display (OCT image)	Yes	Yes	Same
	Retina layer border reference position display (OCT image)	Yes	Yes	Same
	Retina layer border editing function (OCT image)	Yes	Yes	Same
	Anterior segment layer border reference position display (OCT image)	Yes	Yes	Same
	Optic disc shape edit function (OCT image)	Yes	Yes	Same
	3D display video image saving function (OCT image)	Yes	Yes	Same
	Follow-up function	Yes	Yes	Same
Video image acquisition				Same
	Video image recording, saving	Yes	Yes	Same
	Video image viewing	Yes	Yes	Same
Others				Same
	Unit per package	1 unit	1 unit	Same
Standard accessories		Installation Disc, license key, Operator's Manual, Installation Manual	Installation CD, license key, Operator's Manual, Installation Manual	Same
Optional accessories		B-scan Denoising Software	N/A	New function This function denoises a single B-scan image to an averaged image of 120 images added. 120 images can be added with Tracing HD of the OCT unit turned on to obtain a substantially equivalent image. The images denoised by this function are only displayed; the denoised images are not saved nor used for analysis. As described, this function only reduces imaging time, or increases convenience when only B-scan images are read, and does not affect the substantial effectiveness of the function.
		Viewer software plug-in for NAVIS-EX	Viewer software plug-in for NAVIS-EX	Same
		- AL-Scan Viewer	- AL-Scan Viewer	Same
		- CEM Viewer	- CEM Viewer	Same
		- MP Viewer	- MP Viewer	Same

The technical differences between the NAVIS-EX V1.11.0 and the NAVIS-EX V1.5.4 in the Comparison Table above have been assessed through non-clinical testing which demonstrates that the differences do not raise any new questions about safety and effectiveness.

Substantial Equivalence Discussion for the Nidek Mirante per the 510(k) Decision-Making Flowchart

Q1. Are the predicate device(s) legally marketed?

Yes, the predicate device V1.5.4 was cleared in K181345.

Q2. Do the devices have the same intended use?

Yes, both the original software and the new version of the software have the same intended use.

Q3. Do the devices have the same technological characteristics?

Yes, the NAVIS-EX version V1.5.4 includes all functions except for the newly added denoise function.

The differences between the subject device and the predicate device do not raise new questions of safety or effectiveness. The NAVIS-EX is as safe and effective as its predicate device, and thus, may be considered substantially equivalent.

Performance Testing

The NAVIS-EX has been verified for performance and functionality to assure conformance to the requirements for its basic intended use.

The NAVIS-EX compliance the software development lifecycle and the associated verification and validation activities have no unresolved major or critical bugs. A list of testing conducted included:

- Medical device software - Software life cycle processes: IEC 62304: Edition 1.1 2015-06
- Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]: IEC 62366-1: Edition 1.0 2015-02
- Health software - Part 1: General requirements for product safety: IEC 82304-1 Edition 1.0 2016-10

Software documentation has been prepared and submitted for a "moderate" Level of Concern device in accordance with FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.* The device software was verified and validated to support the proposed indications for use according to IEC 62304:2015 *Medical device software – Software life cycle processes* and FDA's *General Principles of Software Validation; Final Guidance for Industry and FDA Staff*.

Risk Analysis

The software device has been assessed to make sure all the risks were sufficiently mitigated according to the intended use. Identification of the associated hazards has been performed in order to evaluate, estimate and control the associated risks in accordance with EN ISO 14971 *Application of risk analysis to medical devices*.

Conclusion

The Nidek Mirante and the NAVIS-EX have the same intended use and similar indications for use, technological characteristics, and principles of operation as the previously cleared predicates.

The Nidek Mirante is technologically and functionally equivalent to the predicate device, Avanti (K180660) for OCT posterior and anterior segment imaging and measurement and to the OPTOS P200DTx (K142897) for posterior segment imaging. The differences between the proposed device, Mirante, and the predicate devices are

not significant and do not raise new issues of safety or effectiveness of the device. The Nidek Mirante is as safe and effective as the predicate devices, and thus, may be considered substantially equivalent.

The Image Filing Software NAVIS -EX has added one function to the previous list of functions available. The B-scan denoise software has been tested and has does not rase new issues of safety or effectiveness of the device. The NAVIS-EX is as safe and effective as the predicate device, and thus, may be considered substantially equivalent.