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JAN 18 2013

510(k) Summary
Optovue, Incorporated
iVue with NDB

This 510(k) summary for the iVue NDB is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

General Information

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Summary Prepared:

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Device Information

Trade Name:	iVue with Normative Database
Common Name:	Optical Coherence Tomography (OCT)
Classification Name:	Ophthalmoscope, a-c powered (21 CFR§ 886.1570)
Classification:	Class II (acc. 21 CFR 886.1570)
Product Code:	HLI

Predicate Devices

(1) iVue® (K091404) - manufactured by Optovue, Inc.
(2) RTVue® with Normative Database (K101505) - manufactured by Optovue, Inc.

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Intended Use

The iVue with Normative Database is an optical coherence tomography system intended for in vivo imaging, axial cross-sectional, three-dimensional imaging and measurement of anterior and posterior ocular structures.

Indications For Use

The iVue is a non-contact, high resolution tomographic imaging device. It is intended for in vivo imaging, axial 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, and anterior chamber of the eye. The iVue with Normative Database is a quantitative tool for the comparison of retina, retinal nerve fiber layer, ganglion cell complex, and optic disc measurements to a database of known normal subjects. The iVue with Normative Database is indicated for use as a device to aid in the diagnosis, documentation, and management of ocular health and diseases in the adult population.

Device Description

iVue with Normative Database (NDB) is a modification of its predicate device iVue (K091404) through the inclusion of the database collected with the iVue. The intent of use, system performance, majority of sub-assemblies, and key components of the iVue with NDB are all the same as iVue and RTVue with NDB.

iVue with NDB, based on the same Optical Coherence Tomography (OCT) technology that is used in the predicate device iVue (K091404) and RTVue with NDB (K101505), is a non-invasive diagnostic device for viewing the ocular tissue structure with micrometer range resolution. Both iVue and RTVue with NDB are designed and manufactured by Optovue, Inc.

The device is currently cleared for in vivo imaging and measurement of the various retinal layers (K091404). The current submission is for a software modification through the addition of a normative database feature, similar to the NDB feature on the cleared predicate device RTVue with NDB (K101505). With the addition of the normative database (NDB), the iVue can compare the measured data from the Retina Map scan, the GCC scan, the Nerve Fiber scan, and the iWellness scan, to the normative database. The iVue/RTVue with Normative Database provide a comparison of the scanned measurements to a database of known normal subjects to provide a reference of where the patient's measurement stands in relation to the normative distribution. The iVue with normative database provides analysis information to be used as a clinical reference to aid in the diagnosis and management of ocular health and diseases. There is no hardware change from the 510(k) cleared iVue System (K091404). Additional scan patterns and acquisition of 3-D disc scan as ONH scan reference, optic disc analysis, and modification of the blood vessel extraction for the retina map scan are other software changes implemented in the current submission. These software changes are similar to features in the predicate RTVue device (K101505) and do not impact the safety and effectiveness of the system.

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The device scans a patient's eye and uses a low coherence interferometer to measure the reflectivity of the retinal and corneal tissue. The cross sectional B-scan of the retinal tissue structure is composed of a sequence of A-scans. It has a traditional patient and instrument interface like most ophthalmic devices. The patient will rest their head on the forehead and chin rest while the operator uses a joystick to align the device to the patient's eye. The computer has a graphic user interface for acquiring and analyzing the image.

iVue with NDB has similar scan patterns and analysis functions as the predicate device RTVue with NDB.

Safety

There is no change in safety from the iVue predicate device (K091404) since this is only a submission to address the addition of an established software database. There is no hardware change in the iVue with Normative Database; therefore, all safety related parameters, such as optical exposure power level, ergonomics, material biocompatibility, and IEC-60601 certification, remain the same as the 510(k) cleared device iVue (K091404). The addition of the NDB has the same indication and analysis features as the predicate device RTVue with NDB (K101505) and does not raise any safety concern.

Effectiveness

The validation of effectiveness of the iVue with NDB has been analyzed in detail. In general, the repeatability and reproducibility of the iVue measurements were reasonably similar to those of the predicate device. The iVue normative database is established using nearly identical methodology as that of the predicate RTVue with NDB. Therefore, the iVue with NDB is as effective as the predicate device, RTVue with NDB (K101505).

Substantial Equivalence

The iVue with NDB is substantially equivalent to the predicate iVue (K091404) and RTVue with NDB (K101505) with regard to intended use, operating principle, function, material, and energy source. Based on the types of measurements, comparisons made to the NDB, size and scope of the NDB, and method employed to establish the NDB limits, the iVue with NDB is substantially equivalent to the predicate device RTVue with NDB. With the exception of the software change associated with the NDB, the iVue with NDB is identical to the predicate 510(k) cleared iVue device (K091404) with regard to operating principle, function, material, and energy source. No mechanical or electrical change has been made. The method of comparing measurements to a normative database for glaucoma and retina pathologies in iVue with NDB is substantially equivalent to the method utilized by the predicate device RTVue with NDB (K101505).

Clinical Evaluation

The equivalence of iVue to RTVue in performing ocular imaging and measurements was established previously (K091409). The validity of the iVue with NDB and its equivalence to predicate devices were evaluated. The iVue normative database collection was based on a similar

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study design, study protocol, and data collection method as those of predicate RTVue NDB data collection. The inclusion and exclusion criteria are identical in the two protocols. The image quality review criteria are similar for both devices. Both the iVue NDB and the RTVue NDB contain a mixture of ethnicities, and have similar age, gender, and refractive error range coverage. The iVue measurements were found to be as repeatable and reproducible as the corresponding measurements of the RTVue. Similar regression models were employed in iVue NDB analysis as those of RTVue with NDB to estimate normative limits. The measurements are similar in normal eyes for both devices. Furthermore, the total number of normal subjects is also similar in the two normative databases. In conclusion, the iVue normative database is substantially equivalent to the predicate device RTVue with NDB.

The iVue NDB study found that age was significantly associated with most study parameters, but the effect of age was small. The iVue NDB study found that SSI was significantly associated with most study parameters; the effect was small and at similar level to the age effect. The RNFL and ONH parameters were found to have strong association with disc area. Gender effect was not significant for most study parameters except for some retina thickness parameters where the retinal thickness was approximately 11μm thinner in female than in male on average.

The comparison of a scan result to the normative database is displayed in color-coded percentile categories as 'within normal', 'borderline', or 'outside normal' based on cut-off levels of 5% for 'borderline' and 1% for 'outside normal', same as in RTVue with NDB which was described in detail in the 510(k) submission (K101505), and received FDA clearance on September 15th 2010. The color categorization of a pixel presents the percentile with regard to the distribution of thickness at the specific location of a given pixel. This database takes into account several important covariates including age, signal strength, and optic disc size for the ONH scans, same as RTVue with NDB.

Performance Data

A repeatability and reproducibility study was conducted with IRB approval to assess iVue precision. Fourteen (14) normal subjects, thirteen (13) patients with glaucoma, and thirteen (13) patients with retina disease were included in the study to evaluate the repeatability and reproducibility of iVue measurements. Only one eye per subject was included in the study. Each study eye was imaged 3 times with each of the 4 scan patterns (ONH, Retina, GCC, and iWellness) per iVue instrument and imaged across 3 instrument/operator pairs. The 3 iVue instruments were operated by different operators, and therefore, the combined effect of machine and operator was estimated for measurement reproducibility.

The precision of iVue measurements was estimated for these parameters (15 retinal parameters from the Retina scan, 5 GCC parameters from the GCC scan, 15 Retinal Nerve Fiber Layer (RNFL) parameters from ONH scan, 9 optic disc parameters from ONH scan, 11 retinal parameters from the iWellness scan, and 5 GCC parameters from the iWellness scan). The precision for each parameter is provided for the i) normal eyes, ii) the retinal disease eyes, and iii) the glaucoma eyes as follow: 1) repeatability standard deviation (SD), 2) reproducibility SD,

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3) coefficient of variation (COV) based on reproducibility (Reproducibility SD/Mean*100), and
4) 95% limits of reproducibility (2.8*Reproducibility SD).

Retina Scan

Table 1. Repeatability and Reproducibility of Retina Thickness (Normal Eyes)

Retina Scan	Normal Eyes (14 subjects, 125 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility COV	Reproducibility Limit*
Fovea (µm)	259.8	3.68	3.78	1.45%	10.5
ParaFovea (µm)	314.5	3.29	3.45	1.10%	9.6
Para S Hemisphere (µm)	316.3	4.11	4.41	1.39%	12.2
Para I Hemisphere (µm)	312.7	3.55	3.57	1.14%	9.9
Para Tempo (µm)	308.0	3.57	3.73	1.21%	10.3
Para Superior (µm)	316.9	4.52	4.92	1.55%	13.6
Para Nasal (µm)	322.6	4.89	4.95	1.53%	13.7
Para Inferior (µm)	310.5	3.97	3.97	1.28%	11.0
Perifovea (µm)	285.9	2.61	2.82	0.99%	7.8
Peri S Hemisphere (µm)	288.6	3.43	3.51	1.22%	9.7
Peri I Hemisphere (µm)	283.2	3.23	3.50	1.24%	9.7
Peri Tempo (µm)	278.1	4.13	4.54	1.63%	12.6
Peri Superior (µm)	287.2	4.34	4.39	1.53%	12.2
Peri Nasal (µm)	301.4	4.26	4.26	1.41%	11.8
Peri Inferior (µm)	277.0	3.90	4.20	1.51%	11.6

* Reproducibility Limit is the 95% limit for the difference between measurements under the reproducibility conditions. Reproducibility Limit = 2.8 x Reproducibility SD per ISO 5725-1 and ISO 5725-6.

Table 2. Repeatability and Reproducibility of Retina Thickness (Retina Disease Eyes)

Retina Scan	Retina Disease Eyes (13 subjects, 110 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility COV	Reproducibility Limit*
Fovea (µm)	286.0	7.74	8.12	2.86%	22.5
ParaFovea (µm)	313.4	2.69	2.86	0.91%	7.9
Para S Hemisphere (µm)	313.5	4.26	4.55	1.45%	12.6
Para I Hemisphere (µm)	313.4	3.04	3.17	1.01%	8.8
Para Tempo (µm)	303.6	4.22	4.28	1.41%	11.9
Para Superior (µm)	313.1	5.83	6.05	1.94%	16.8
Para Nasal (µm)	323.2	5.00	5.08	1.57%	14.1
Para Inferior (µm)	313.9	3.85	3.91	1.25%	10.8
Perifovea (µm)	280.2	1.58	1.66	0.59%	4.6
Peri S Hemisphere (µm)	283.1	2.76	2.88	1.02%	8.0
Peri I Hemisphere (µm)	277.4	3.57	3.94	1.42%	10.9
Peri Tempo (µm)	268.3	3.37	3.62	1.35%	10.0
Peri Superior (µm)	283.1	3.69	3.84	1.36%	10.6
Peri Nasal (µm)	295.8	3.61	3.68	1.25%	10.2
Peri Inferior (µm)	273.7	4.94	5.63	2.06%	15.6

* Reproducibility Limit is the 95% limit for the difference between measurements under the reproducibility conditions. Reproducibility Limit = 2.8 x Reproducibility SD per ISO 5725-1 and ISO 5725-6.

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Table 3. Repeatability and Reproducibility of Retina Thickness (Glaucoma Eyes)

Retina Scan	Glaucoma Eyes (13 subjects, 101 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility COV	Reproducibility Limit*
Fovea (µm)	255.9	5.18	5.64	2.18%	15.6
ParaFovea (µm)	294.6	2.34	2.50	0.85%	6.9
Para S Hemisphere (µm)	295.5	2.60	3.09	1.04%	8.6
Para I Hemisphere (µm)	293.8	2.92	2.92	0.99%	8.1
Para Tempo (µm)	289.5	2.79	2.99	1.03%	8.3
Para Superior (µm)	295.4	3.03	3.66	1.23%	10.1
Para Nasal (µm)	300.9	3.47	3.47	1.15%	9.6
Para Inferior (µm)	292.7	3.52	3.52	1.20%	9.8
Perifovea (µm)	267.4	1.76	2.21	0.82%	6.1
Peri S Hemisphere (µm)	271.0	2.60	2.77	1.02%	7.7
Peri I Hemisphere (µm)	263.9	3.08	3.99	1.51%	11.1
Peri Tempo (µm)	262.6	4.34	4.40	1.67%	12.2
Peri Superior (µm)	269.6	3.12	3.35	1.24%	9.3
Peri Nasal (µm)	279.2	3.67	3.89	1.39%	10.8
Peri Inferior (µm)	258.3	3.82	5.08	1.96%	14.1

* Reproducibility Limit is the 95% limit for the difference between measurements under the reproducibility conditions. Reproducibility Limit = 2.8 x Reproducibility SD per ISO 5725-1 and ISO 5725-6.

GCC Scan

Table 4. Repeatability and Reproducibility of GCC (Normal Eyes)

GCC Scan	Normal Eyes (14 subjects, 124 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility COV	Reproducibility Limit*
GCC_Average (µm)	95.4	1.49	1.52	1.59%	4.2
GCC_Superior_Avg (µm)	95.5	1.83	1.87	1.96%	5.2
GCC_Inferior_Avg (µm)	95.3	1.43	1.44	1.51%	4.0
GCC_FLV (%)	1.213	0.438	0.438	35.97%	1.214
GCC_GLV (%)	4.999	1.043	1.072	21.52%	2.972

* Reproducibility Limit is the 95% limit for the difference between measurements under the reproducibility conditions. Reproducibility Limit = 2.8 x Reproducibility SD per ISO 5725-1 and ISO 5725-6.

** The high COV values for GCC_FLV and GCC_GLV is due to the highly skewed distribution near zero values of normal eyes and the denominator for the COV calculation has a low value. COV is not an appropriate measure of test-retest variability for such skewed distributions with a large portion of data at or near zero. Please interpret the data with this information in mind.

Table 5. Repeatability and Reproducibility of GCC (Retina Disease Eyes)

GCC Scan	Retina Disease Eyes (13 subjects, 98 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility COV	Reproducibility Limit*
GCC_Average (µm)	96.2	2.08	2.24	2.34%	6.2
GCC_Superior_Avg (µm)	96.7	2.65	2.88	3.00%	8.0
GCC_Inferior_Avg (µm)	95.7	2.15	2.22	2.33%	6.2
GCC_FLV (%)	2.628	0.688	0.694	26.54%	1.925
GCC_GLV (%)	5.557	1.066	1.116	19.02%	3.093

* Reproducibility Limit is the 95% limit for the difference between measurements under the reproducibility conditions. Reproducibility Limit = 2.8 x Reproducibility SD per ISO 5725-1 and ISO 5725-6.

** The high COV values for GCC_FLV and GCC_GLV is due to the highly skewed distribution near zero values of normal eyes and the denominator for the COV calculation has a low value. COV is not an appropriate measure of test-retest variability for such skewed distributions with a large portion of data at or near zero. Please interpret the data with this information in mind.

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Table 6. Repeatability and Reproducibility of GCC (Glaucoma Eyes)

GCC Scan	Glaucoma Eyes (13 subjects, 109 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility COV	Reproducibility Limit*
GCC_Average (µm)	83.2	1.91	1.91	2.29%	5.3
GCC_Superior_Avg (µm)	84.6	2.21	2.21	2.62%	6.1
GCC_Inferior_Avg (µm)	81.8	2.33	2.33	2.84%	6.5
GCC_FLV (%)	4.273	1.116	1.116	26.99%	3.094
GCC_GLV (%)	15.164	1.676	1.676	11.10%	4.644

* Reproducibility Limit is the 95% limit for the difference between measurements under the reproducibility conditions. Reproducibility Limit = 2.8 x Reproducibility SD per ISO 5725-1 and ISO 5725-6.

** The high COV values for GCC_FLV and GCC_GLV is due to the highly skewed distribution near zero values of normal eyes and the denominator for the COV calculation has a low value. COV is not an appropriate measure of test-retest variability for such skewed distributions with a large portion of data at or near zero. Please interpret the data with this information in mind.

iWellness Scan

Note that 11 retina thickness parameters are provided for iWellness scan retinal measurements; the 4 hemisphere parameters (Para S Hemisphere, Para I Hemisphere, Peri S Hemisphere, and Peri I Hemisphere) are not included in the iWellness scan report.

Table 7. Repeatability and Reproducibility of GCC and Retina Thickness (Normal Eyes)

iWellness Scan	Normal Eyes (14 subjects, 125 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility COV	Reproducibility Limit*
	GCC Parameters				
GCC_Average (µm)	94.6	1.15	1.17	1.24%	3.2
GCC_Superior_Avg (µm)	94.7	1.42	1.45	1.53%	4.0
GCC_Inferior_Avg (µm)	94.5	1.18	1.19	1.26%	3.3
GCC_FLV (%)	1.029	0.458	0.458	44.43%	1.269
GCC_GLV (%)	5.117	0.588	0.635	12.33%	1.759
	Retina Parameters				
Fovea (µm)	257.8	2.29	3.10	1.20%	8.6
ParaFovea (µm)	316.3	3.62	3.71	1.17%	10.3
Para Tempo (µm)	306.6	3.75	3.89	1.27%	10.8
Para Superior (µm)	321.2	4.56	4.60	1.43%	12.8
Para Nasal (µm)	320.8	4.75	4.75	1.48%	13.2
Para Inferior (µm)	316.6	3.76	3.98	1.26%	11.0
Perifovea (µm)	286.9	2.74	2.79	0.97%	7.7
Peri Tempo (µm)	279.4	4.01	4.22	1.51%	11.7
Peri Superior (µm)	290.2	3.87	3.92	1.35%	10.9
Peri Nasal (µm)	301.4	4.16	4.16	1.38%	11.5
Peri Inferior (µm)	276.6	2.99	3.09	1.12%	8.6

* Reproducibility Limit is the 95% limit for the difference between measurements under the reproducibility conditions. Reproducibility Limit = 2.8 x Reproducibility SD per ISO 5725-1 and ISO 5725-6.

** The high COV values for GCC_FLV and GCC_GLV is due to the highly skewed distribution near zero values of normal eyes and the denominator for the COV calculation has a low value. COV is not an appropriate measure of test-retest variability for such skewed distributions with a large portion of data at or near zero. Please interpret the data with this information in mind.

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Table 8. Repeatability and Reproducibility of GCC and Retina Thickness (Retina Disease Eyes)

iWellness Scan	Retina Disease Eyes (13 subjects, 108 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility COV	Reproducibility Limit*
	GCC Parameters				
GCC_Average (µm)	95.3	1.56	1.68	1.76%	4.6
GCC_Superior_Avg (µm)	95.3	1.87	1.98	2.08%	5.5
GCC_Inferior_Avg (µm)	95.3	1.67	1.75	1.84%	4.9
GCC_FLV (%)	2.716	0.533	0.538	20.25%	1.490
GCC_GLV (%)	5.972	0.811	0.845	14.11%	2.343
	Retina Parameters				
Fovea (µm)	280.6	4.17	4.37	1.55%	12.1
ParaFovea (µm)	314.2	2.65	2.76	0.88%	7.7
Para Tempo (µm)	305.2	3.79	4.21	1.38%	11.7
Para Superior (µm)	317.0	3.71	3.91	1.23%	10.8
Para Nasal (µm)	319.8	5.17	5.17	1.62%	14.3
Para Inferior (µm)	314.8	3.16	3.24	1.03%	9.0
Perifovea (µm)	281.1	1.73	1.92	0.69%	5.3
Peri Tempo (µm)	272.5	3.48	4.01	1.48%	11.1
Peri Superior (µm)	284.6	2.32	2.36	0.83%	6.5
Peri Nasal (µm)	293.9	2.56	2.63	0.90%	7.3
Peri Inferior (µm)	273.6	2.47	2.74	1.00%	7.6

* Reproducibility Limit is the 95% limit for the difference between measurements under the reproducibility conditions. Reproducibility Limit = 2.8 x Reproducibility SD per ISO 5725-1 and ISO 5725-6.

** The high COV values for GCC_FLV and GCC_GLV is due to the highly skewed distribution near zero values of normal eyes and the denominator for the COV calculation has a low value. COV is not an appropriate measure of test-retest variability for such skewed distributions with a large portion of data at or near zero. Please interpret the data with this information in mind.

Table 9. Repeatability and Reproducibility of GCC and Retina Thickness (Glaucoma Eyes)

iWellness Scan	Glaucoma Eyes (13 subjects, 106 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility COV	Reproducibility Limit*
	GCC Parameters				
GCC_Average (µm)	82.4	1.14	1.14	1.38%	3.2
GCC_Superior_Avg (µm)	83.3	1.62	1.62	1.93%	4.5
GCC_Inferior_Avg (µm)	81.5	1.56	1.57	1.92%	4.3
GCC_FLV (%)	3.943	0.913	0.929	23.28%	2.575
GCC_GLV (%)	15.636	0.934	0.934	6.07%	2.588
	Retina Parameters				
Fovea (µm)	254.6	2.87	3.01	1.18%	8.3
ParaFovea (µm)	296.4	2.24	2.30	0.77%	6.4
Para Tempo (µm)	289.5	2.64	2.75	0.95%	7.6
Para Superior (µm)	299.0	2.84	2.87	0.96%	8.0
Para Nasal (µm)	299.6	3.10	3.10	1.03%	8.6
Para Inferior (µm)	297.3	2.98	3.01	1.01%	8.3
Perifovea (µm)	267.6	1.63	1.78	0.67%	4.9
Peri Tempo (µm)	263.8	4.02	4.18	1.58%	11.6
Peri Superior (µm)	270.2	2.14	2.14	0.79%	5.9
Peri Nasal (µm)	278.5	2.99	2.99	1.07%	8.3
Peri Inferior (µm)	257.7	2.40	2.68	1.04%	7.4

* Reproducibility Limit is the 95% limit for the difference between measurements under the reproducibility conditions. Reproducibility Limit = 2.8 x Reproducibility SD per ISO 5725-1 and ISO 5725-6.

** The high COV values for GCC_FLV and GCC_GLV is due to the highly skewed distribution near zero values of normal eyes and the denominator for the COV calculation has a low value. COV is not an appropriate measure of test-retest variability for such skewed distributions with a large portion of data at or near zero. Please interpret the data with this information in mind.

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ONH Scan

Table 10. Repeatability and Reproducibility of Disc and RNFL Thickness (Normal Eyes)

ONH Scan	Normal Eyes (14 subjects, 123 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility COV	Reproducibility Limit*
Disc Parameters					
discArea (mm²)	1.929	0.084	0.086	4.42%	0.237
Area_C_D_ratio	0.316	0.020	0.021	6.66%	0.058
H_C_D_ratio	0.592	0.043	0.045	7.69%	0.126
V_C_D_ratio	0.479	0.028	0.030	6.29%	0.083
CupArea (mm²)	0.623	0.038	0.042	6.73%	0.116
RimArea (mm²)	1.306	0.074	0.077	5.89%	0.214
RimVolume (mm³)	0.157	0.014	0.015	9.23%	0.040
Nervehead_Volume (mm³)	0.314	0.040	0.043	13.59%	0.119
CupVolume (mm³)	0.129	0.021	0.023	17.91%	0.063
RNFL Parameters					
Avg_RNFL (µm)	97.7	1.27	1.38	1.42%	3.8
Sup_RNFL (µm)	99.1	1.47	1.47	1.48%	4.1
Inf_RNFL (µm)	96.3	1.99	2.19	2.27%	6.1
Tempo (µm)	74.3	3.95	3.95	5.33%	10.9
Superior (µm)	116.2	3.27	3.38	2.91%	9.4
Nasal (µm)	74.8	2.87	2.90	3.86%	8.0
Inferior (µm)	125.4	3.51	3.70	2.95%	10.2
TU (µm)	82.2	5.31	5.36	6.53%	14.8
ST (µm)	133.2	5.05	5.16	3.88%	14.3
SN (µm)	99.3	4.83	4.83	4.87%	13.4
NU (µm)	81.6	3.63	3.63	4.43%	10.1
NL (µm)	68.0	2.82	3.07	4.50%	8.5
IN (µm)	109.5	4.59	4.81	4.39%	13.3
IT (µm)	141.3	5.22	5.26	3.72%	14.6
TL (µm)	66.3	3.43	3.43	5.18%	9.5

* Reproducibility Limit is the 95% limit for the difference between measurements under the reproducibility conditions. Reproducibility Limit = 2.8 x Reproducibility SD per ISO 5725-1 and ISO 5725-6.

Table 11. Repeatability and Reproducibility of Disc and RNFL Thickness (Retinal Disease Eyes)

ONH Scan	Retina Disease Eyes (13 subjects, 101 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility COV	Reproducibility Limit*
Disc Parameters					
discArea (mm²)	2.226	0.068	0.068	3.14%	0.189
Area_C_D_ratio	0.357	0.021	0.021	5.72%	0.059
H_C_D_ratio	0.600	0.036	0.036	5.91%	0.100
V_C_D_ratio	0.518	0.058	0.060	11.35%	0.167
CupArea (mm²)	0.837	0.044	0.044	5.21%	0.121
RimArea (mm²)	1.390	0.065	0.065	4.85%	0.180
RimVolume (mm³)	0.144	0.013	0.013	9.30%	0.035
Nervehead_Volume (mm³)	0.311	0.033	0.033	11.23%	0.092
CupVolume (mm³)	0.139	0.020	0.020	14.81%	0.057
RNFL Parameters					
Avg_RNFL (µm)	99.4	1.50	1.77	1.81%	4.9
Sup_RNFL (µm)	100.1	2.12	2.55	2.59%	7.1
Inf_RNFL (µm)	98.7	2.15	2.17	2.23%	6.0
Tempo (µm)	74.0	3.27	3.62	4.95%	10.0
Superior (µm)	116.2	4.35	4.63	4.05%	12.8
Nasal (µm)	79.7	3.54	3.54	4.53%	9.8
Inferior (µm)	127.6	3.30	3.32	2.65%	9.2
TU (µm)	83.1	5.33	5.96	7.25%	16.5
ST (µm)	126.9	6.51	7.06	5.68%	19.6
SN (µm)	105.4	4.76	4.79	4.59%	13.3
NU (µm)	84.7	4.37	4.37	5.32%	12.1
NL (µm)	74.6	3.55	3.55	4.79%	9.8
IN (µm)	126.1	4.88	4.88	4.01%	13.5
IT (µm)	129.2	4.81	5.03	3.90%	14.0
TL (µm)	64.9	3.42	3.42	5.33%	9.5

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* Reproducibility Limit is the 95% limit for the difference between measurements under the reproducibility conditions. Reproducibility Limit = 2.8 x Reproducibility SD per ISO 5725-1 and ISO 5725-6.

Table 12. Repeatability and Reproducibility of Disc and RNFLThickness (Glaucoma Eyes)

ONH Scan	Glaucoma Eyes (13 subjects, 112 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility COV	Reproducibility Limit*
Disc Parameters					
discArea (mm²)	2.324	0.052	0.060	2.59%	0.167
Area_C_D_ratio	0.630	0.020	0.020	3.16%	0.055
H_C_D_ratio	0.806	0.020	0.020	2.47%	0.055
V_C_D_ratio	0.754	0.033	0.034	4.47%	0.093
CupArea (mm²)	1.528	0.044	0.046	2.99%	0.127
RimArea (mm²)	0.795	0.054	0.057	7.08%	0.158
RimVolume (mm³)	0.053	0.010	0.010	18.23%	0.027
Nervehead_Volume (mm³)	0.130	0.024	0.024	18.10%	0.066
CupVolume (mm³)	0.443	0.043	0.048	10.79%	0.133
RNFL Parameters					
Avg_RNFL (µm)	84.6	1.48	1.55	1.83%	4.3
Sup_RNFL (µm)	89.1	1.95	1.99	2.24%	5.5
Inf_RNFL (µm)	80.2	2.09	2.13	2.66%	5.9
Tempo (µm)	66.4	2.93	3.15	4.77%	8.7
Superior (µm)	104.5	3.01	3.13	2.99%	8.7
Nasal (µm)	66.6	2.20	2.33	3.50%	6.4
Inferior (µm)	101.1	2.54	2.56	2.52%	7.1
TU (µm)	72.7	3.71	4.12	5.68%	11.4
ST (µm)	117.4	4.17	4.52	3.85%	12.5
SN (µm)	91.7	3.84	3.84	4.18%	10.6
NU (µm)	74.8	3.55	3.71	4.98%	10.3
NL (µm)	58.4	1.94	1.98	3.40%	5.5
IN (µm)	91.9	3.08	3.08	3.32%	8.5
IT (µm)	110.3	4.73	4.76	4.32%	13.2
TL (µm)	60.0	4.70	4.76	7.97%	13.2

* Reproducibility Limit is the 95% limit for the difference between measurements under the reproducibility conditions. Reproducibility Limit = 2.8 x Reproducibility SD per ISO 5725-1 and ISO 5725-6.

In addition, all 4 scan types and measurement parameters available in iVue with NDB are compared to the predicate RTVue with NDB device (K101505). Table 13 – 18 summarize the number of eyes in each study group, mean measurement for the new device and the predicate device, mean (& standard deviation) of the differences, 95% confidence interval for the mean differences, and 95% limits of agreement for each parameter and each scan type.

iVue GCC vs. RTVue GCC	Subjects (n)	Mean_of _iVue	Mean_of _RTVue	mean_of_ Differences	STDEV_of_ Differences	95%CI_of_mean_ of_Differences	LOA_ lower_bound	LOA_ upper_bound
Normal Group								
GCC_Average (µm)	21	95.65	96.90	-1.25	2.92	(-2.577, 0.077)	-7.77	5.27
GCC_Superior_Avg (µm)	21	95.89	97.25	-1.37	2.89	(-2.681, -0.049)	-8.14	5.41
GCC_Inferior_Avg (µm)	21	95.41	96.55	-1.13	3.21	(-2.595, 0.325)	-8.10	5.83
GCC_FLV (%)	21	1.083	0.813	0.270	0.757	(-0.074, 0.614)	-1.519	2.059
GCC_GLV (%)	21	3.964	4.146	-0.182	1.857	(-1.027, 0.662)	-4.266	3.901
Glaucoma Group								
GCC_Average (µm)	24	79.10	80.44	-1.34	1.50	(-1.974, -0.709)	-5.31	2.62
GCC_Superior_Avg (µm)	24	79.75	80.76	-1.01	2.66	(-2.133, 0.114)	-7.35	5.34
GCC_Inferior_Avg (µm)	24	78.45	80.13	-1.67	2.17	(-2.591, -0.758)	-6.99	3.64
GCC_FLV (%)	24	4.641	4.854	-0.213	1.328	(-0.773, 0.347)	-3.445	3.019
GCC_GLV (%)	24	14.648	16.813	-2.165	1.095	(-2.626, -1.702)	-5.280	0.951

Table 13. iVue GCC vs. RTVue GCC in normal and glaucoma groups

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iVue ONH vs. RTVue ONH (Disc Parameters)	Subjects (n)	Mean_of_iVue	Mean_of_RTVue	mean_of_Differences	STDEV_of_Differences	95%CI_of_mean_of_Differences	LOA_lower_bound	LOA_upper_bound
Normal Group								
discArea (mm^2)	21	1.916	2.090	-0.174	0.180	(-0.256 , -0.092)	-0.528	0.179
Area_C_D_ratio	21	0.300	0.261	0.038	0.044	(0.018 , 0.0580)	-0.057	0.134
H_C_D_ratio	21	0.566	0.595	-0.029	0.087	(-0.068 , 0.010)	-0.221	0.163
V_C_D_ratio	21	0.462	0.479	-0.017	0.057	(-0.042, 0.009)	-0.142	0.108
CupArea (mm^2)	21	0.584	0.549	0.035	0.076	(0.000, 0.069)	-0.136	0.205
RimArea (mm^2)	21	1.332	1.541	-0.209	0.187	(-0.294, -0.124)	-0.586	0.167
RimVolume (mm^3)	21	0.159	0.236	-0.077	0.097	(-0.121, -0.032)	-0.320	0.166
Nervehead_Volume (mm^3)	21	0.334	0.409	-0.075	0.094	(-0.118, -0.032)	-0.320	0.169
CupVolume (mm^3)	21	0.112	0.116	-0.004	0.028	(-0.016, 0.009)	-0.067	0.060
Glaucoma Group								
discArea (mm^2)	23	2.035	1.952	0.083	0.246	(-0.023, 0.189)	-0.399	0.566
Area_C_D_ratio	23	0.599	0.586	0.013	0.089	(-0.025, 0.052)	-0.202	0.228
H_C_D_ratio	23	0.800	0.854	-0.054	0.075	(-0.086, -0.021)	-0.220	0.113
V_C_D_ratio	23	0.708	0.789	-0.081	0.093	(-0.120, -0.040)	-0.283	0.122
CupArea (mm^2)	23	1.243	1.149	0.095	0.211	(0.003, 0.186)	-0.375	0.565
RimArea (mm^2)	23	0.792	0.802	-0.011	0.222	(-0.106, 0.085)	-0.503	0.482
RimVolume (mm^3)	23	0.068	0.067	0.001	0.019	(-0.006, 0.009)	-0.040	0.042
Nervehead_Volume (mm^3)	23	0.151	0.128	0.023	0.038	(0.006, 0.039)	-0.061	0.107
CupVolume (mm^3)	23	0.341	0.328	0.013	0.095	(-0.028, 0.054)	-0.212	0.237

Table 14. iVue ONH vs. RTVue ONH (Disc Parameters) in normal and glaucoma groups

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iVue ONH vs. RTVue ONH (RNFL Parameters)	Subjects (n)	Mean_of_iVue	Mean_of_RTVue	mean_of_Differences	STDEV_of_Differences	95%CI_of_mean_of_Differences	LOA_lower_bound	LOA_upper_bound
Normal Group								
Avg_RNFL (µm)	21	100.42	104.85	-4.43	3.15	(-5.862, -2.991)	-11.56	2.70
Sup_RNFL (µm)	21	101.53	103.75	-2.23	5.28	(-4.630, 0.179)	-13.53	9.08
Inf_RNFL (µm)	21	99.31	105.94	-6.63	4.54	(-8.697, -4.562)	-16.73	3.47
Tempo (µm)	21	78.43	84.33	-5.91	6.20	(-8.728, -3.085)	-21.60	9.79
Superior (µm)	21	118.17	121.79	-3.62	7.61	(-7.083, -0.154)	-19.38	12.14
Nasal (µm)	21	74.99	78.76	-3.77	6.60	(-6.776, -0.765)	-20.26	12.71
Inferior (µm)	21	130.09	134.50	-4.41	6.50	(-7.369, -1.451)	-18.30	9.48
TU (µm)	21	87.96	86.81	1.15	9.26	(-3.067, 5.362)	-20.61	22.90
ST (µm)	21	135.64	134.82	0.82	6.96	(-2.352, 3.988)	-14.57	16.20
SN (µm)	21	100.70	108.76	-8.05	10.89	(-13.008, -3.096)	-30.71	14.60
NU (µm)	21	81.80	84.62	-2.82	8.28	(-6.583, 0.951)	-21.32	15.69
NL (µm)	21	68.18	72.97	-4.80	6.11	(-7.576, -2.016)	-22.89	13.30
IN (µm)	21	111.51	119.78	-8.27	7.89	(-11.864, -4.679)	-30.04	13.50
IT (µm)	21	148.68	149.21	-0.54	8.71	(-4.502, 3.430)	-21.51	20.44
TL (µm)	21	68.89	81.82	-12.93	6.39	(-15.837, -10.022)	-29.47	3.61
Glaucoma Group								
Avg_RNFL (µm)	23	78.17	81.54	-3.37	3.19	(-4.750, -1.989)	-10.26	3.52
Sup_RNFL (µm)	23	79.49	81.45	-1.96	3.89	(-3.644, -0.283)	-10.63	6.71
Inf_RNFL (µm)	23	76.86	81.64	-4.78	4.79	(-6.847, -2.708)	-14.89	5.33
Tempo (µm)	23	59.48	63.83	-4.36	4.82	(-6.442, -2.275)	-16.20	7.48
Superior (µm)	23	93.17	96.03	-2.86	6.37	(-5.614, -0.105)	-16.47	10.75
Nasal (µm)	23	63.19	66.37	-3.18	5.06	(-5.369, -0.990)	-15.56	9.20
Inferior (µm)	23	96.87	99.96	-3.08	7.63	(-6.382, 0.214)	-18.88	12.71
TU (µm)	23	64.95	64.15	0.80	6.00	(-1.796, 3.391)	-13.91	15.51
ST (µm)	23	102.82	99.61	3.21	7.73	(-0.134, 6.547)	-13.74	20.16
SN (µm)	23	83.52	92.41	-8.90	8.42	(-12.534, -5.255)	-26.56	8.77
NU (µm)	23	66.67	69.61	-2.94	5.05	(-5.127, -0.757)	-15.74	9.86
NL (µm)	23	59.70	63.16	-3.46	6.82	(-6.409, -0.514)	-19.45	12.52
IN (µm)	23	88.54	96.69	-8.14	9.29	(-12.160, -4.128)	-27.44	11.15
IT (µm)	23	105.20	103.24	1.96	9.23	(-2.035, 5.948)	-17.36	21.27
TL (µm)	23	54.00	63.49	-9.49	6.48	(-12.293, -6.689)	-24.65	5.67

Table 15. iVue ONH vs. RTVue ONH (RNFL Parameters) in normal and glaucoma groups

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iVue Retina Map vs. RTVue EMM5	Subjects (n)	Mean_of _iVue	Mean_of _RTVue	mean_of_ Differences	STDEV_of_ Differences	95%CI_of_mean_ of_Differences	LOA_ lower_bound	LOA_ upper_bound
Normal Group								
Fovea (µm)	21	260.21	258.65	1.56	4.29	(-0.395, 3.510)	-9.07	12.18
ParaFovea (µm)	21	314.79	319.40	-4.61	6.87	(-7.736, -1.485)	-18.68	9.45
Para S Hemisphere (µm)	21	316.34	322.04	-5.70	7.97	(-9.325, -2.071)	-22.09	10.69
Para I Hemisphere (µm)	21	313.25	316.82	-3.57	6.38	(-6.475, -0.667)	-16.87	9.73
Para Tempo (µm)	21	307.67	310.90	-3.23	7.47	(-6.625, 0.173)	-18.75	12.30
Para Superior (µm)	21	317.09	323.86	-6.76	8.66	(-10.704, -2.821)	-24.63	11.10
Para Nasal (µm)	21	322.71	325.90	-3.18	8.01	(-6.828, 0.463)	-20.19	13.82
Para Inferior (µm)	21	311.70	316.89	-5.19	6.56	(-8.177, -2.208)	-18.90	8.51
Perifovea (µm)	21	286.43	290.16	-3.73	5.95	(-6.441, -1.026)	-15.93	8.46
Peri S Hemisphere (µm)	21	289.58	291.01	-1.43	6.26	(-4.281, 1.419)	-14.45	11.58
Peri I Hemisphere (µm)	21	283.27	289.27	-6.00	6.85	(-9.115, -2.876)	-20.72	8.72
Peri Tempo (µm)	21	278.59	282.36	-3.77	9.33	(-8.012, 0.478)	-24.20	16.67
Peri Superior (µm)	21	288.50	287.40	1.11	6.14	(-1.687, 3.903)	-12.38	14.59
Peri Nasal (µm)	21	301.59	308.02	-6.43	6.15	(-9.229, -3.629)	-19.75	6.89
Peri Inferior (µm)	21	277.02	282.75	-5.73	7.98	(-9.359, -2.094)	-22.92	11.46
Retina Group								
Fovea (µm)	19	297.60	293.11	4.50	1.85	(3.605, 5.386)	-4.94	13.93
ParaFovea (µm)	19	327.57	325.25	2.31	5.37	(-0.276, 4.902)	-9.23	13.85
Para S Hemisphere (µm)	19	330.69	327.29	3.40	9.61	(-1.233, 8.026)	-16.89	23.69
Para I Hemisphere (µm)	19	324.45	323.31	1.14	3.67	(-0.628, 2.911)	-7.77	10.06
Para Tempo (µm)	19	328.04	324.88	3.16	7.11	(-0.266, 6.588)	-12.07	18.39
Para Superior (µm)	19	330.69	327.51	3.18	13.22	(-3.189, 9.551)	-24.66	31.02
Para Nasal (µm)	19	331.07	327.80	3.27	7.18	(-0.195, 6.729)	-13.08	19.62
Para Inferior (µm)	19	320.48	320.95	-0.47	4.62	(-2.699, 1.755)	-11.96	11.02
Perifovea (µm)	19	291.19	288.67	2.52	5.05	(0.089, 4.954)	-7.76	12.81
Peri S Hemisphere (µm)	19	294.75	290.30	4.45	10.48	(-0.595, 9.504)	-16.69	25.60
Peri I Hemisphere (µm)	19	287.62	287.08	0.55	5.49	(-2.101, 3.192)	-11.16	12.25
Peri Tempo (µm)	19	288.82	285.95	2.87	6.29	(-0.161, 5.902)	-11.91	17.65
Peri Superior (µm)	19	292.12	286.32	5.80	14.20	(-1.046, 12.638)	-22.99	34.58
Peri Nasal (µm)	19	303.39	301.97	1.42	8.79	(-2.816, 5.653)	-17.15	19.99
Peri Inferior (µm)	19	280.42	280.37	0.06	7.52	(-3.568, 3.678)	-15.59	15.70

Table 16. iVue Retina Map vs. RTVue EMM5 in normal and retina groups

iVue iWellness vs. RTVue GCC (GCC Parameters)	Subjects (n)	Mean_of _iVue	Mean_of _RTVue	mean_of_ Differences	STDEV_of_ Differences	95%CI_of_mean_ of_Differences	LOA_ lower_bound	LOA_ upper_bound
Normal Group								
GCC_Average (µm)	21	95.01	96.86	-1.86	2.65	(-3.062, -0.650)	-7.73	4.02
GCC_Superior_Avg (µm)	21	95.30	97.14	-1.85	2.72	(-3.085, -0.608)	-8.15	4.46
GCC_Inferior_Avg (µm)	21	94.73	96.59	-1.86	2.83	(-3.150, -0.573)	-8.01	4.29
GCC_FLV (%)	21	0.976	0.784	0.193	0.652	(-0.104, 0.489)	-1.351	1.736
GCC_GLV (%)	21	3.871	4.259	-0.389	1.802	(-1.208, 0.431)	-4.118	3.340
Glaucoma Group								
GCC_Average (µm)	23	79.13	81.11	-1.98	1.78	(-2.752, -1.208)	-6.21	2.25
GCC_Superior_Avg (µm)	23	79.14	81.42	-2.27	2.47	(-3.340, -1.206)	-8.05	3.51
GCC_Inferior_Avg (µm)	23	79.10	80.79	-1.69	1.72	(-2.429, -0.944)	-6.11	2.73
GCC_FLV (%)	23	5.056	4.504	0.552	1.085	(0.082, 1.020)	-2.249	3.352
GCC_GLV (%)	23	12.672	16.125	-3.453	1.645	(-4.164, -2.741)	-7.353	0.447

Table 17. iVue iWellness vs. RTVue GCC (GCC Parameters) in normal and glaucoma groups

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iVue iWellness vs. RTVue EMM5 (Retina Parameters)	Subjects (n)	Mean_of_iVue	Mean_of_RTVue	mean_of_Differences	STDEV_of_Differences	95%CI_of_mean_of_Differences	LOA_lower_bound	LOA_upper_bound
Normal Group								
Fovea (µm)	21	258.40	258.61	-0.20	5.55	(-2.730, 2.323)	-12.05	11.64
ParaFovea (µm)	21	317.10	317.75	-0.65	7.15	(-3.902, 2.611)	-15.20	13.91
Para S Hemisphere (µm)	21	318.63	319.73	-1.10	8.64	(-5.032, 2.837)	-18.60	16.41
Para I Hemisphere (µm)	21	315.57	315.64	-0.08	6.40	(-2.988, 2.838)	-13.30	13.15
Para Tempo (µm)	21	307.71	310.16	-2.45	8.43	(-6.290, 1.387)	-19.70	14.79
Para Superior (µm)	21	322.94	321.44	1.50	8.64	(-2.433, 5.432)	-16.16	19.16
Para Nasal (µm)	21	320.39	323.54	-3.15	8.15	(-6.857, 0.563)	-20.23	13.94
Para Inferior (µm)	21	317.36	315.58	1.78	7.16	(-1.482, 5.039)	-12.95	16.50
Perifovea (µm)	21	287.25	288.26	-1.02	6.08	(-3.783, 1.749)	-13.32	11.28
Peri S Hemisphere (µm)	21	290.94	289.63	1.31	7.14	(-1.941, 4.555)	-13.26	15.87
Peri I Hemisphere (µm)	21	283.55	286.92	-3.37	6.53	(-6.342, -0.401)	-17.02	10.27
Peri Tempo (µm)	21	278.40	279.97	-1.57	8.95	(-5.646, 2.506)	-20.47	17.33
Peri Superior (µm)	21	290.76	286.32	4.44	7.79	(0.896, 7.989)	-11.65	20.53
Peri Nasal (µm)	21	302.44	306.66	-4.22	7.97	(-7.850, -0.593)	-20.64	12.20
Peri Inferior (µm)	21	277.38	280.06	-2.68	7.61	(-6.144, 0.787)	-18.80	13.45
Retina Group								
Fovea (µm)	16	278.96	276.71	2.24	3.71	(0.269, 4.218)	-6.09	10.57
ParaFovea (µm)	16	318.55	315.23	3.32	4.94	(0.684, 5.953)	-6.77	13.41
Para S Hemisphere (µm)	16	320.32	317.10	3.22	6.65	(-0.325, 6.757)	-10.42	16.85
Para I Hemisphere (µm)	16	316.78	313.46	3.32	5.40	(0.442, 6.193)	-7.83	14.47
Para Tempo (µm)	16	311.60	308.58	3.02	7.33	(-0.885, 6.922)	-12.85	18.88
Para Superior (µm)	16	323.57	319.10	4.47	8.32	(0.037, 8.901)	-12.51	21.45
Para Nasal (µm)	16	322.46	321.10	1.36	5.41	(-1.523, 4.242)	-10.37	13.08
Para Inferior (µm)	16	316.55	312.29	4.26	6.37	(0.869, 7.655)	-9.11	17.64
Perifovea (µm)	16	285.46	283.14	2.33	5.60	(-0.658, 5.313)	-8.99	13.65
Peri S Hemisphere (µm)	16	289.42	285.44	3.99	10.05	(-1.367, 9.338)	-16.35	24.32
Peri I Hemisphere (µm)	16	281.50	280.84	0.66	3.97	(-1.458, 2.775)	-7.95	9.27
Peri Tempo (µm)	16	275.39	271.74	3.65	4.65	(1.171, 6.128)	-8.39	15.69
Peri Superior (µm)	16	288.93	283.61	5.31	12.99	(-1.607, 12.231)	-20.95	31.57
Peri Nasal (µm)	16	301.53	301.41	0.12	7.71	(-3.990, 4.228)	-16.20	16.44
Peri Inferior (µm)	16	276.01	275.66	0.35	5.87	(-2.776, 3.484)	-12.11	12.82

Table 18. iVue iWellness vs. RTVue EMM5 (Retina Parameters) in normal and retina groups

In general, the repeatability and reproducibility of the iVue measurements were reasonably similar to those of the predicate device. The iVue normative database measurements are similar to the predicate device in normative values, and have similar behavior with respect to the effects of patient age, signal strength, and optic disc size. In conclusion, based on the studies and tests performed, the iVue with normative database is substantially equivalent to the predicate devices, RTVue with NDB (K101505).

Conclusion

As described in this 510(k) Summary, all necessary testing and analyses were completed on the iVue with Normative Database to ensure that the device is substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 18, 2013

Optovue, Inc.
% Mr. Jay Wei
President & CEO
45531 Northport Loop W
Fremont, CA 94538

Re: K121739
Trade/Device Name: iVue with Normative Database
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: HLI
Dated: January 7, 2013
Received: January 9, 2013

Dear Mr. Wei:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Opthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

optovue

Statement of Indications for Use

510(k) Number (if known): K121739

Device Name: iVue with Normative Database

Indications for Use:

The iVue is a non-contact, high resolution tomographic imaging device. It is intended for in vivo imaging, axial 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, and anterior chamber of the eye. The iVue with Normative Database is a quantitative tool for the comparison of retina, retinal nerve fiber layer, ganglion cell complex, and optic disc measurements to a database of known normal subjects. The iVue with Normative Database is indicated for use as a device to aid in the diagnosis, documentation, and management of ocular health and diseases in the adult population.

Prescription Use ___X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number K121739