510(k) SUMMARY

510(k) Notification K133132

GENERAL INFORMATION

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DEVICE INFORMATION

Trade Name:
OPTICAL BIOMETER AL-Scan

Generic/Common Name:
AC-powered Slitlamp Biomicroscope

Classification:
21 CFR §886.1850, Class II
21 CFR §892.1560, Class II

Product Code:
HJO
IYO

PREDICATE DEVICE(S)

- LenStar LS 900 (K082891)
- PacScan 300 (K843696)
- EchoScan Model US-1800 (K020876)
- Pentacam (K030719)

INDICATIONS FOR USE

OPTICAL BIOMETER AL-Scan Indications for Use

The OPTICAL BIOMETER AL-Scan is a medical device that optically measures eye components such as:

- axial length;
- corneal thickness;
- anterior chamber depth;
- corneal curvature radii;
- corneal cylinder axis;
- white-to-white distance; and
- pupil diameter.

Axial length and corneal thickness can also be measured using ultrasound.

The OPTICAL BIOMETER AL-Scan also performs calculations to assist physicians in determining the power of the intraocular lens for implantation.

Diagnostic Ultrasound Indications for Use

System: OPTICAL BIOMETER AL-Scan
Transducer: A-scan probe
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 &3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other * (Specify)
Ophthalmic	Ophthalmic							N (A-mode)
Fetal Imaging & Other	Fetal							
	Abdominal							
Fetal Imaging & Other	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 &3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other * (Specify)
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel							
	Other (Specif6)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

System: OPTICAL BIOMETER AL-Scan
Transducer: Pachymetry probe
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 &3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other * (Specify)
Ophthalmic	Ophthalmic							N (A-mode)
Fetal Imaging & Other	Fetal							
	Abdominal							
Fetal Imaging & Other	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 &3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other * (Specify)
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel							
	Other (Specif6)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

PRODUCT DESCRIPTION

The OPTICAL BIOMETER AL-Scan ("AL-Scan") measures ocular measurements including: axial length, corneal thickness, anterior chamber depth, corneal curvature radii, corneal cylinder axis, white-to-white distance, and pupil diameter. It measures these necessary values successively through a non-contact optical measurement method. The AL-Scan measures as a single unit the values necessary to calculate the power of an IOL for cataract surgery.

Two optional ultrasonic probes (A-scan Probe and Pachymetry Probe) are available for use in the event the optical measurement is unsuccessful. The A-scan probe scans the axial length, anterior chamber depth, lens thickness and the pachymetry probe scans the corneal thickness. Both probes utilize an ultrasonic measurement function by touching the probe to the cornea.

The AL-Scan also has the function to calculate the power of an IOL using measured values such as axial length.

SUBSTANTIAL EQUIVALENCE

The OPTICAL BIOMETER AL-Scan is similar in technological characteristics, performance and has similar indications for use as the predicate devices. Any differences in technological characteristics between the proposed device and the predicate devices do not raise any new issues of safety or effectiveness. Thus, the OPTICAL BIOMETER AL-Scan is substantially equivalent to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary bench and clinical testing was conducted on the OPTICAL BIOMETER AL-Scan to support a determination of substantial equivalence to the predicate devices. The tests performed include:

- Ophthalmic Testing per ISO 15004-1 and ISO 15004-2
- Clinical Accuracy and System Sensitivity Testing

- Acoustic Output Testing
- Software Verification and Validation
- Usability Testing
- Electrical Safety and Electromagnetic Compatibility
- Prospective Comparative Clinical Study for Precision and Agreement to the predicate devices. (Summary of results are provided below.)

The collective performance testing demonstrate that the AL-Scan does not raise any new questions of safety or effectiveness when compared to the predicate devices. The results of the performance testing demonstrate that the OPTICAL BIOMETER AL-Scan performs as intended.

Summary of Clinical Results

Nidek conducted a prospective clinical study at a single U.S. clinical site assessing the agreement of the OPTICAL BIOMETER AL-Scan to the predicate, LenStar LS 900 (Haag-Streit AG), as well as an ultrasound reference device, the PacScan 300A (Sonomed). The study also assessed the precision of the OPTICAL BIOMETER AL-Scan and the LenStar LS 900. The study utilized three OPTICAL BIOMETER AL-Scan devices, three predicate devices and one ultrasound reference device. Subjects were enrolled for each portion of the study, Agreement and Precision, in equal number from four eye populations. The four eye populations consisted of:

1. Normal eyes (phakic eyes without cataracts or corneal disease);
2. Eyes with cataracts;
3. Eyes without a natural lens (including aphakic and pseudophakic eyes); and
4. Eyes with corneal abnormality (including eyes post-keratorefractive surgery).

For the Agreement portion of the study, each study eye was measured once with a randomly selected OPTICAL BIOMETER AL-Scan device, once with a randomly selected predicate device and once with the ultrasound reference device. For the Precision portion of the study, each study eye was measured three times on each of the three OPTICAL BIOMETER AL-Scan devices (a total of 9 measures) and three times on each of the three predicate devices (a total of 9 measures).

Agreement Results

Eighty (80) subject eyes were assessed in the Agreement portion of the study, 20 eyes in each of the four eye populations.

Table 1 provides a summary of the agreement results for axial length, keratometry, corneal cylinder axis, anterior chamber depth, central corneal thickness, white-to-white distance and pupil diameter for the OPTICAL BIOMETER AL-Scan and LenStar LS 900, for all eye populations combined. Table 2 provides a summary of the agreement results summarized by eye population.

Table 1: Summary of Ophthalmic Biometry Agreement Results for the AL-Scan and LenStar LS 900 (All Eye Populations Combined)

Measure	AL-Scan (Mean±SD)	LenStar LS 900 (Mean±SD)	Difference (Mean±SD)	95% CI for Mean Difference	95% LoA for Difference
Axial Length (mm)	N=80 24.12 ± 1.44	N=80 24.13 ± 1.45	N=80 -0.007 ± 0.029	[-0.014; -0.001]	-0.063, 0.049
Keratometry SE (mm)	N=80 7.744 ± 0.435	N=79 7.784 ± 0.373	N=79 -0.015 ± 0.043	[-0.025; -0.005]	-0.100, 0.070
Corneal Cylinder Axis (°), with Cylinder < 0.75 D	N=56 86 ± 61	N=55 89 ± 59	N=55 -9.0 ± 27.4	[-16.4; -1.6]	-62.8, 44.7
Corneal Cylinder Axis (°), with Cylinder ≥ 0.75 D	N=24 111 ± 63	N=24 89 ± 64	N=24 -0.8 ± 6.6	[-3.6; 2.1]	-13.8, 12.3
Anterior Chamber Depth (mm)	N=59 3.43 ± 0.38	N=77 3.68 ± 0.64[†]	N=59 0.021 ± 0.049	[0.008; 0.034]	-0.075, 0.118
Central Corneal Thickness (μ)	N=79 533 ± 42	N=80 531 ± 45	N=79 -0.0 ± 8.3	[-1.9; 1.8]	-16.3, 16.2
White-to-White Distance (mm)	N=79 12.1 ± 0.4	N=80 12.2 ± 0.5	N=79 -0.15 ± 0.14	[-0.18; -0.12]	-0.42, 0.12
Pupil Diameter (mm)	N=78 4.6 ± 1.1	N=79 4.5 ± 1.0	N=77 0.15 ± 0.60	[0.01; 0.29]	-1.03, 1.33

Source: Summary.sas (20FEB14 11:59)

[†] The LenStar LS 900 results for the anterior chamber depth include the results from the "Eyes without a Natural Lens Population"

Table 2: Summary of Ophthalmic Biometry Agreement Results for the AL-Scan and LenStar LS 900 (by Eye Population)

Measure	AL-Scan (Mean±SD)	LenStar LS 900 (Mean±SD)	Difference (Mean±SD)	95% CI for Mean Difference	95% LoA for Difference
Eye Population: Normal					
Axial Length (mm)	N=20 23.52 ± 1.26	N=20 23.52 ± 1.27	N=20 -0.003 ± 0.021	[-0.013; 0.006]	-0.044, 0.037
Keratometry SE (mm)	N=20 7.600 ± 0.255	N=20 7.611 ± 0.255	N=20 -0.011 ± 0.021	[-0.021; -0.001]	-0.053, 0.031
Corneal Cylinder Axis (°), with Cylinder < 0.75 D	N=13 73 ± 61	N=13 93 ± 59	N=13 -6.2 ± 19.1	[-17.8; 5.3]	-43.7, 31.3
Corneal Cylinder Axis (°), with Cylinder ≥ 0.75 D	N=7 121 ± 75	N=7 73 ± 78	N=7 -3.1 ± 3.0	[-5.9; -0.4]	-9.0, 2.7
Anterior Chamber Depth (mm)	N=20 3.45 ± 0.34	N=20 3.42 ± 0.34	N=20 0.028 ± 0.043	[0.008; 0.048]	-0.056, 0.112
Central Corneal Thickness (μ)	N=20 536 ± 29	N=20 538 ± 32	N=20 -1.6 ± 6.8	[-4.7; 1.6]	-14.9, 11.8
White-to-White Distance (mm)	N=20 12.1 ± 0.5	N=20 12.2 ± 0.6	N=20 -0.18 ± 0.16	[-0.26; -0.11]	-0.50, 0.13
Pupil Diameter (mm)	N=20 4.9 ± 0.9	N=20 5.0 ± 0.8	N=20 -0.06 ± 0.53	[-0.31; 0.18]	-1.10, 0.98

Table 2: Summary of Ophthalmic Biometry Agreement Results for the AL-Scan and LenStar LS 900 (by Eye Population) – cont.

Measure	AL-Scan (Mean±SD)	LenStar LS 900 (Mean±SD)	Difference (Mean±SD)	95% CI for Mean Difference	95% LoA for Difference
Eye Population: Cataract					
Axial Length (mm)	N=20 24.19 ± 1.24	N=20 24.21 ± 1.26	N=20 -0.017 ± 0.035	[-0.033; -0.001]	-0.086, 0.052
Keratometry SE (mm)	N=20 7.763 ± 0.261	N=20 7.773 ± 0.250	N=20 -0.010 ± 0.040	[-0.029; 0.009]	-0.089, 0.069
Corneal Cylinder Axis (°), with Cylinder < 0.75 D	N=15 104 ± 56	N=15 82 ± 60	N=15 -13.1 ± 25.9	[-27.5; 1.2]	-63.8, 37.6
Corneal Cylinder Axis (°), with Cylinder ≥ 0.75 D	N=5 73 ± 73	N=5 74 ± 71	N=5 -1.0 ± 5.7	[-8.0; 6.0]	-12.1, 10.1
Anterior Chamber Depth (mm)	N=20 3.22 ± 0.40	N=20 3.22 ± 0.39	N=20 -0.001 ± 0.040	[-0.019; 0.018]	-0.079, 0.078
Central Corneal Thickness (μ)	N=20 540 ± 32	N=20 539 ± 34	N=20 0.5 ± 8.2	[-3.4; 4.3]	-15.5, 16.4
White-to-White Distance (mm)	N=19 12.0 ± 0.4	N=20 12.2 ± 0.4	N=19 -0.19 ± 0.12	[-0.24; -0.13]	-0.42, 0.04
Pupil Diameter (mm)	N=20 4.2 ± 1.3	N=19 3.9 ± 0.8	N=19 0.40 ± 0.61	[0.11; 0.69]	-0.79, 1.59

Table 2: Summary of Ophthalmic Biometry Agreement Results for the AL-Scan and LenStar LS 900 (by Eye Population) – cont.

Measure	AL-Scan (Mean±SD)	LenStar LS 900 (Mean±SD)	Difference (Mean±SD)	95% CI for Mean Difference	95% LoA for Difference
Eye Population: Without a Natural Lens					
Axial Length (mm)	N=20 23.77 ± 0.73	N=20 23.77 ± 0.73	N=20 0.002 ± 0.013	[-0.004; 0.008]	-0.023, 0.027
Keratometry SE (mm)	N=20 7.709 ± 0.245	N=20 7.738 ± 0.233	N=20 -0.030 ± 0.050	[-0.053; -0.006]	-0.127, 0.068
Corneal Cylinder Axis (°), with Cylinder < 0.75 D	N=13 98 ± 65	N=13 80 ± 63	N=13 -9.8 ± 38.8	[-33.3; 13.6]	-86.0, 66.3
Corneal Cylinder Axis (°), with Cylinder ≥ 0.75 D	N=7 98 ± 38	N=7 98 ± 34	N=7 0.1 ± 8.3	[-7.5; 7.8]	-16.1, 16.4
Anterior Chamber Depth (mm)	--	N=17 4.67 ± 0.31	--	--	--
Central Corneal Thickness (μ)	N=20 554 ± 32	N=20 553 ± 31	N=20 0.7 ± 8.1	[-3.1; 4.5]	-15.1, 16.5
White-to-White Distance (mm)	N=20 12.1 ± 0.5	N=20 12.2 ± 0.5	N=20 -0.08 ± 0.11	[-0.13; -0.03]	-0.30, 0.14
Pupil Diameter (mm)	N=18 4.1 ± 0.7	N=20 3.9 ± 0.6	N=18 0.16 ± 0.40	[-0.04; 0.36]	-0.62, 0.94

Table 2: Summary of Ophthalmic Biometry Agreement Results for the AL-Scan and LenStar LS 900 (by Eye Population) – cont.

Measure	AL-Scan (Mean±SD)	LenStar LS 900 (Mean±SD)	Difference (Mean±SD)	95% CI for Mean Difference	95% LoA for Difference
Eye Population: Corneal Abnormality					
Axial Length (mm)	N=20 25.01 ± 1.89	N=20 25.02 ± 1.92	N=20 -0.010 ± 0.037	[-0.027; 0.007]	-0.083, 0.063
Keratometry SE (mm)	N=20 7.904 ± 0.736	N=19 8.024 ± 0.562	N=19 -0.009 ± 0.054	[-0.035; 0.017]	-0.116, 0.097
Corneal Cylinder Axis (°), with Cylinder < 0.75 D	N=15 70 ± 62	N=14 102 ± 60	N=14 -6.4 ± 25.2	[-21.0; 8.1]	-55.9, 43.0
Corneal Cylinder Axis (°), with Cylinder ≥ 0.75 D	N=5 152 ± 52	N=5 114 ± 78	N=5 1.6 ± 9.3	[-9.9; 13.1]	-16.6, 19.8
Anterior Chamber Depth (mm)	N=19 3.64 ± 0.28	N=20 3.58 ± 0.28	N=19 0.037 ± 0.058	[0.009; 0.065]	-0.076, 0.150
Central Corneal Thickness (μ)	N=19 502 ± 53	N=20 495 ± 57	N=19 0.3 ± 10.3	[-4.7; 5.2]	-19.9, 20.4
White-to-White Distance (mm)	N=20 12.2 ± 0.4	N=20 12.3 ± 0.4	N=20 -0.16 ± 0.14	[-0.22; -0.09]	-0.43, 0.12
Pupil Diameter (mm)	N=20 5.2 ± 1.2	N=20 5.1 ± 1.0	N=20 0.11 ± 0.75	[-0.24; 0.47]	-1.36, 1.59

Source: Summary.sas (20FEB14 11:59)

Table 3 provides a summary of the agreement results for axial length and anterior chamber depth for the OPTICAL BIOMETER AL-Scan and PacScan 300A, for all eye populations combined. Table 4 provides a summary of the agreement results summarized by eye population.

Table 3: Summary of Ophthalmic Biometry Agreement Results for the AL-Scan and PacScan 300A (All Eye Populations Combined)

Measure	AL-Scan (Mean±SD)	PacScan 300A (Mean±SD)	Difference (Mean±SD)	95% CI for Mean Difference	95% LoA for Difference
Axial Length (mm)	N=80 24.12 ± 1.44	N=80 24.09 ± 1.30	N=80 0.034 ± 0.241	[-0.019; 0.088]	-0.439, 0.507
Anterior Chamber Depth (mm)	N=59 3.43 ± 0.38	N=80 3.44 ± 0.55*	N=59 0.172 ± 0.244	[0.109; 0.235]	-0.305, 0.649

Source: Summary.sas (20FEB14 11:59)

* The PacScan 300A results for the anterior chamber depth include the results from the "Eyes without a Natural Lens Population".

Table 4: Summary of Ophthalmic Biometry Agreement Results for the AL-Scan and PacScan 300A (by Eye Population)

Measure	AL-Scan (Mean±SD)	PacScan 300A (Mean±SD)	Difference (Mean±SD)	95% CI for Mean Difference	95% LoA for Difference
Eye Population: Normal					
Axial Length (mm)	N=20 23.52 ± 1.26	N=20 23.47 ± 1.24	N=20 0.042 ± 0.091	[-0.001; 0.084]	-0.138, 0.221
Anterior Chamber Depth (mm)	N=20 3.45 ± 0.34	N=20 3.30 ± 0.48	N=20 0.147 ± 0.239	[0.035; 0.258]	-0.322, 0.615
Eye Population: Cataract					
Axial Length (mm)	N=20 24.19 ± 1.24	N=20 24.11 ± 1.13	N=20 0.080 ± 0.207	[-0.016; 0.177]	-0.325, 0.486
Anterior Chamber Depth (mm)	N=20 3.22 ± 0.40	N=20 3.04 ± 0.51	N=20 0.180 ± 0.225	[0.075; 0.285]	-0.261, 0.621
Eye Population: Without a Natural Lens					
Axial Length (mm)	N=20 23.77 ± 0.73	N=20 23.93 ± 0.74	N=20 -0.153 ± 0.198	[-0.246; -0.061]	-0.542, 0.235
Anterior Chamber Depth (mm)	--	N=20 3.95 ± 0.35	--	--	--
Eye Population: Corneal Abnormality					
Axial Length (mm)	N=20 25.01 ± 1.89	N=20 24.84 ± 1.65	N=20 0.168 ± 0.306	[0.025; 0.312]	-0.431, 0.768
Anterior Chamber Depth (mm)	N=19 3.64 ± 0.28	N=20 3.47 ± 0.41	N=19 0.191 ± 0.276	[0.058; 0.323]	-0.350, 0.731

Source: Summary.sas (20FEB14 11:59)

The OPTICAL BIOMETER AL-Scan demonstrated agreement to the LenStar LS 900 for the assessment of axial length, keratometry, corneal cylinder axis, central corneal thickness, white-to-white distance and pupil diameter and to the PacScan 300A for axial length. The OPTICAL BIOMETER AL-Scan also demonstrated agreement to the LenStar LS 900 and the PacScan 300A for the assessment of anterior chamber depth in normal eyes, eyes with cataracts and eyes with a corneal abnormality. The OPTICAL BIOMETER Al-Scan was unable to determine the anterior chamber depth for eyes without a natural lens.

Precision Results

Forty (40) subject eyes were assessed in the Precision portion of the study, 10 eyes in each of four eye populations.

Table 5 provides the coefficient of variation (CV) and standard deviation (SD) for reproducibility and repeatability along with the sample size and mean for the OPTICAL BIOMETER AL-Scan, for all eye populations combined.

Table 5: AL-Scan Precision Analysis with Reproducibility and Repeatability Coefficient of Variation (CV) (All Eye Populations Combined)

			Reproducibility		Repeatability	
Measure	**Number of Eyes**	**Mean**	**SD**	**% CV**	**SD**	**% CV**
Axial Length (mm)	40	24.025	0.034	0.1%	0.034	0.1%
Keratometry SE (mm)	40	7.796	0.060	0.8%	0.060	0.8%
Corneal Cylinder Axis (°), with Cylinder < 0.75 D	18	76.6	13.3	17.4%	13.2	17.2%
Corneal Cylinder Axis (°), with Cylinder ≥ 0.75 D	22	88.5	4.0	4.5%	3.8	4.3%
Anterior Chamber Depth† (mm)	30	3.453	0.033	1.0%	0.019	0.5%
Central Corneal Thickness (μ)	40	541.2	4.5	0.8%	3.6	0.7%
White-to-White Distance (mm)	40	12.11	0.27	2.2%	0.26	2.2%
Pupil Diameter (mm)	40	4.47	0.37	8.3%	0.34	7.7%

Source: prec_pooled.sas (10MAR14 13:54)
† Excludes eyes without a natural lens.

Table 6 provides the coefficient of variation (CV) and standard deviation (SD) for reproducibility and repeatability along with the sample size and mean for the OPTICAL BIOMETER AL-Scan, by eye population.

Table 6: AL-Scan Precision Analysis with Reproducibility and Repeatability Coefficient of Variation (CV) (by Eye Population)

			Reproducibility		Repeatability	
Measure	**Number of Eyes**	**Mean**	**SD**	**% CV**	**SD**	**% CV**
Eye Population: Normal						
Axial Length (mm)	10	23.743	0.045	0.2%	0.045	0.2%
Keratometry SE (mm)	10	7.672	0.112	1.5%	0.112	1.5%
Corneal Cylinder Axis (°), with Cylinder < 0.75 D	4	64.6	5.5	8.4%	5.0	7.7%
Corneal Cylinder Axis (°), with Cylinder ≥ 0.75 D	6	69.8	5.2	7.4%	4.7	6.7%
Anterior Chamber Depth (mm)	10	3.455	0.027	0.8%	0.019	0.5%
Central Corneal Thickness (μ)	10	539.7	4.9	0.9%	1.7	0.3%
White-to-White Distance (mm)	10	12.15	0.06	0.5%	0.06	0.5%
Pupil Diameter (mm)	10	5.06	0.39	7.8%	0.36	7.2%

Table 6: AL-Scan Precision Analysis with Reproducibility and Repeatability Coefficient of Variation (CV) (by Eye Population) – cont.

			Reproducibility		Repeatability	
Measure	**Number of Eyes**	**Mean**	**SD**	**% CV**	**SD**	**% CV**
Eye Population: Cataract						
Axial Length (mm)	10	24.047	0.009	0.0%	0.008	0.0%
Keratometry SE (mm)	10	7.696	0.025	0.3%	0.023	0.3%
Corneal Cylinder Axis (°), with Cylinder < 0.75 D	2	94.2	10.8	11.4%	9.6	10.2%
Corneal Cylinder Axis (°), with Cylinder ≥ 0.75 D	8	100.2	3.1	3.1%	3.0	3.0%
Anterior Chamber Depth (mm)	10	3.311	0.051	1.5%	0.041	1.2%
Central Corneal Thickness (μ)	10	554.2	5.4	1.0%	2.4	0.4%
White-to-White Distance (mm)	10	12.12	0.21	1.7%	0.21	1.7%
Pupil Diameter (mm)	10	3.75	0.36	9.7%	0.31	8.3%
Eye Population: Without a Natural Lens						
Axial Length (mm)	10	23.529	0.007	0.0%	0.006	0.0%
Keratometry SE (mm)	10	7.632	0.022	0.3%	0.021	0.3%
Corneal Cylinder Axis (°), with Cylinder < 0.75 D	6	97.4	19.3	19.9%	19.3	19.9%
Corneal Cylinder Axis (°), with Cylinder ≥ 0.75 D	4	81.2	4.8	5.9%	4.6	5.7%
Anterior Chamber Depth (mm)	0	--	--	--	--	--
Central Corneal Thickness (μ)	10	578.6	3.8	0.7%	2.3	0.4%
White-to-White Distance (mm)	10	11.84	0.45	3.8%	0.44	3.7%
Pupil Diameter (mm)	10	3.70	0.24	6.4%	0.21	5.6%

Table 6: AL-Scan Precision Analysis with Reproducibility and Repeatability Coefficient of Variation (CV) (by Eye Population) – cont.

			Reproducibility		Repeatability	
Measure	**Number of Eyes**	**Mean**	**SD**	**% CV**	**SD**	**% CV**
Eye Population: Corneal Abnormality						
Axial Length (mm)	10	24.781	0.051	0.2%	0.051	0.2%
Keratometry SE (mm)	10	8.181	0.030	0.4%	0.029	0.3%
Corneal Cylinder Axis (°), with Cylinder < 0.75 D	6	58.0	10.5	18.2%	10.1	17.5%
Corneal Cylinder Axis (°), with Cylinder ≥ 0.75 D	4	100.5	2.5	2.5%	2.1	2.1%
Anterior Chamber Depth (mm)	10	3.603	0.034	1.0%	0.027	0.7%
Central Corneal Thickness (μ)	10	490.4	5.5	1.1%	2.3	0.5%
White-to-White Distance (mm)	10	12.33	0.21	1.7%	0.20	1.7%
Pupil Diameter (mm)	10	5.35	0.46	8.5%	0.43	8.0%

Source: Prec_by_Pop.sas (10MAR14 14:15)

Table 7 provides the coefficient of variation (CV) and standard deviation (SD) for reproducibility and repeatability along with the sample size and mean for the LenStar LS 900, for all eye populations combined.

Table 7: LenStar LS 900 Precision Analysis with Reproducibility and Repeatability Coefficient of Variation (CV) (All Eye Populations Combined)

			Reproducibility		Repeatability	
Measure	**Number of Eyes**	**Mean**	**SD**	**% CV**	**SD**	**% CV**
Axial Length (mm)	40	23.998	0.266	1.1%	0.264	1.1%
Keratometry SE (mm)	40	7.805	0.034	0.4%	0.033	0.4%
Corneal Cylinder Axis (°), with Cylinder < 0.75 D	15	74.8	7.9	10.6%	7.9	10.6%
Corneal Cylinder Axis (°), with Cylinder ≥ 0.75 D	25	81.9	5.1	6.2%	5.0	6.1%
Anterior Chamber Depth (mm)	39	3.680	0.097	2.6%	0.097	2.6%
Central Corneal Thickness (μ)	40	542.4	1.8	0.3%	1.8	0.3%
White-to-White Distance (mm)	40	12.26	0.11	0.9%	0.11	0.9%
Pupil Diameter (mm)	39	4.49	0.47	10.4%	0.44	9.8%

Source: prec_pooled.sas (10MAR14 13:54)

Table 8 provides the coefficient of variation (CV) and standard deviation (SD) for reproducibility and repeatability along with the sample size and mean for the LenStar LS 900, by eye population.

Table 8: LenStar LS 900 Precision Analysis with Reproducibility and Repeatability Coefficient of Variation (CV) (by Eye Population)

			Reproducibility		Repeatability	
Measure	**Number of Eyes**	**Mean**	**SD**	**% CV**	**SD**	**% CV**
Eye Population: Normal						
Axial Length (mm)	10	23.760	0.013	0.1%	0.010	0.0%
Keratometry SE (mm)	10	7.679	0.012	0.2%	0.012	0.2%
Corneal Cylinder Axis (°), with Cylinder < 0.75 D	4	64.9	6.4	9.8%	5.7	8.8%
Corneal Cylinder Axis (°), with Cylinder ≥ 0.75 D	6	69.9	2.9	4.2%	2.8	4.0%
Anterior Chamber Depth (mm)	10	3.401	0.024	0.7%	0.024	0.7%
Central Corneal Thickness (μ)	10	541.3	1.4	0.3%	1.4	0.3%
White-to-White Distance (mm)	10	12.28	0.10	0.8%	0.10	0.8%
Pupil Diameter (mm)	10	4.81	0.47	9.8%	0.42	8.7%

Table 8: LenStar LS 900 Precision Analysis with Reproducibility and Repeatability Coefficient of Variation (CV) (by Eye Population) – cont.

			Reproducibility		Repeatability	
Measure	**Number of Eyes**	**Mean**	**SD**	**% CV**	**SD**	**% CV**
Eye Population: Cataract						
Axial Length (mm)	10	23.911	0.536	2.2%	0.513	2.1%
Keratometry SE (mm)	10	7.704	0.011	0.1%	0.011	0.1%
Corneal Cylinder Axis (°), with Cylinder < 0.75 D	1	39.4	11.8	29.8%	6.3	16.1%
Corneal Cylinder Axis (°), with Cylinder ≥ 0.75 D	9	107.0	3.0	2.8%	2.9	2.7%
Anterior Chamber Depth (mm)	10	3.311	0.009	0.3%	0.008	0.2%
Central Corneal Thickness (μ)	10	557.8	1.6	0.3%	1.5	0.3%
White-to-White Distance (mm)	10	12.27	0.08	0.6%	0.07	0.6%
Pupil Diameter (mm)	10	3.86	0.35	9.0%	0.32	8.2%
Eye Population: Without a Natural Lens						
Axial Length (mm)	10	23.526	0.009	0.0%	0.007	0.0%
Keratometry SE (mm)	10	7.637	0.020	0.3%	0.020	0.3%
Corneal Cylinder Axis (°), with Cylinder < 0.75 D	6	90.7	8.7	9.5%	8.6	9.5%
Corneal Cylinder Axis (°), with Cylinder ≥ 0.75 D	4	58.5	8.5	14.5%	7.8	13.4%
Anterior Chamber Depth (mm)	9	4.617	0.039	0.9%	0.039	0.9%
Central Corneal Thickness (μ)	10	578.8	1.7	0.3%	1.7	0.3%
White-to-White Distance (mm)	10	11.98	0.16	1.3%	0.16	1.3%
Pupil Diameter (mm)	9	4.06	0.39	9.7%	0.39	9.7%

Table 8: LenStar LS 900 Precision Analysis with Reproducibility and Repeatability Coefficient of Variation (CV) (by Eye Population) – cont.

			Reproducibility		Repeatability	
Measure	**Number of Eyes**	**Mean**	**SD**	**% CV**	**SD**	**% CV**
Eye Population: Corneal Abnormality						
Axial Length (mm)	10	24.794	0.011	0.0%	0.008	0.0%
Keratometry SE (mm)	10	8.200	0.063	0.8%	0.060	0.7%
Corneal Cylinder Axis (°), with Cylinder < 0.75 D	4	69.3	8.6	12.4%	8.6	12.4%
Corneal Cylinder Axis (°), with Cylinder ≥ 0.75 D	6	71.9	6.3	8.8%	6.1	8.5%
Anterior Chamber Depth (mm)	10	3.546	0.021	0.6%	0.020	0.6%
Central Corneal Thickness (μ)	10	491.6	2.3	0.5%	2.3	0.5%
White-to-White Distance (mm)	10	12.50	0.07	0.5%	0.07	0.5%
Pupil Diameter (mm)	10	5.08	0.55	10.8%	0.48	9.5%

Source: Prec_by_Pop.sas (10MAR14 14:15)

The reproducibility and repeatability for the OPTICAL BIOMETER AL-Scan is considered to be comparable to the LenStar LS 900 for axial length, keratometry, corneal cylinder axis, central corneal thickness, white-to-white distance and pupil diameter. Similarly, the reproducibility and repeatability for the OPTICAL BIOMETER AL-Scan was comparable to the LenStar LS 900 for anterior chamber depth in normal eyes, eyes with cataracts and eyes with a corneal abnormality. The OPTICAL BIOMETER AL-Scan was unable to determine the anterior chamber depth for eyes without a natural lens.

IOL Power Calculations

IOL power calculations were performed for subjects in the Agreement Portion of the study. The calculations were successfully performed using the Regression, Regression II, Formula/T, Holladay, Hoffer-Q, Haigis and Binkhorst Formulas for all eyes. In addition, the Camellin-Calossi and Shammas-PL IOL power calculation formulas were successfully performed for subjects in the corneal abnormality eye population that previously had keratorefractive surgery.

Safety Results

There were no safety events associated with the OPTICAL BIOMETER AL-Scan, the predicate device, or the reference devices utilized for this study.

Clinical Study Conclusions

The OPTICAL BIOMETER AL-Scan demonstrated agreement to the predicate device, LenStar LS 900, and the ultrasound reference device, PacScan 300A. The precision of the OPTICAL BIOMETER AL-Scan is considered to be comparable to the predicate device. The OPTICAL BIOMETER AL-Scan is capable of providing the specified IOL power calculations. The OPTICAL BIOMETER AL-Scan has the necessary accuracy and precision for its intended use.

CONCLUSION

In summary, Nidek Co., Ltd. is of the opinion that the OPTICAL BIOMETER AL-Scan does not introduce any new potential safety risks, is as effective and performs as well as the predicate devices, and concludes that the OPTICAL BIOMETER AL-Scan is substantially equivalent to the predicate devices.

SUMMARY

The OPTICAL BIOMETER AL-Scan is substantially equivalent to the 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

June 11, 2014

Nidek Co., Ltd.
c/o Ms. Darlene Crockett-Billig
Experian Group, LLC.
755 N. Mathilda Ave., Suite 100
Sunnyvale, CA 94085

Re: K133132
Trade/Device Name: OPTICAL BIOMETER AL-Scan
Regulation Number: 21 CFR 886.1850
Regulation Name: Biomicroscope, Slit-Lamp, AC-powered
Regulatory Class: Class II
Product Code: HJO, IYO
Dated: May 6, 2014
Received: May 7, 2014

Dear Ms. Crockett-Billig:

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,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133132

Device Name
OPTICAL BIOMETER AL-Scan

Indications for Use *(Describe)*
The OPTICAL BIOMETER AL-Scan is a medical device that optically measures eye components such as:

- axial length;
- corneal thickness;
- anterior chamber depth;
- corneal curvature radii;
- corneal cylinder axis;
- white-to-white distance; and
- pupil diameter.

Axial length and corneal thickness can also be measured using ultrasound.

The OPTICAL BIOMETER AL-Scan also performs calculations to assist physicians in determining the power of the intraocular lens for implantation.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Jan C. Callaway -S
2014.06.05 13:34:23 -04'00'

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INDICATIONS FOR USE STATEMENT (CONT.)

Diagnostic Ultrasound Indications for Use

510(k) Number: K133132

System: OPTICAL BIOMETER AL-Scan

Transducer: A-scan probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							N (A-mode)
	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
Fetal Imaging & Other	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

INDICATIONS FOR USE STATEMENT (CONT.)

Diagnostic Ultrasound Indications for Use

510(k) Number: K133132

System: OPTICAL BIOMETER AL-Scan

Transducer: Pachymetry probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							N (A-mode)
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix