February 2, 2021

Huvitz Co., Ltd.
% Dave Kim
CEO
Mtech Group
7707 Fannin St. Ste 200
Houston, Texas 77054

Re: K202097
Trade/Device Name: Fundus Camera
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic camera
Regulatory Class: Class II
Product Code: HKI
Dated: December 28, 2020
Received: December 28, 2020

Dear Dave Kim:

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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202097

Device Name
HFC-1 Fundus Camera

Indications for Use *(Describe)*

HFC-1 fundus camera is intended to capture digital images for the anterior and retina segment of the eye without the use of a mydriatic agent. It is intended for use as an aid to clinicians in the evaluation and diagnosis of ocular health.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

General Information

- Manufacturer: Huvitz Co., Ltd.
38, Burim-ro 170beon-gil,
Dongan-gu, Anyang-si, Gyeonggi-do,
14055, Republic of Korea
Phone: 82-31-428-9100
Fax: 82-31-477-8617

- Contact Person: Dave Kim
Mtech Group.
7707 Fannin St. Ste 200-V111, Houston, TX 77054
Tel: +713-467-2607
E-mail: davekim@mtech-inc.net

Device Information:

- Classification: Class II
- Proprietary Name: HFC-1
- Classification Name: Camera, Ophthalmic, ac-powered
- Regulation No: 21 CFR 886.1120 (HKI)
- Common Name: Fundus Camera

Predicate Device Information:

- Trade Name: Non-Mydriatic Auto Fundus Camera Nidek AFC-330
- Classification Name: HKI, Ophthalmic Camera, AC power
- 510(k) Number: K113451

Indication for Use:

HFC-1 fundus camera is intended to capture digital images for the anterior and retina segment of the eye without the use of a mydriatic agent. It is intended for use as an aid to clinicians in the evaluation and diagnosis of ocular health.

Intended Use:

HFC-1 Fundus camera is a non-contact, high-resolution bio-microscopic imaging device. It is indicated for in-vivo viewing, color fundus image using a color camera without the use of mydiatic agents. HFC-1 Fundus camera captures fundus image to assist a clinician for diagnostic examinations.

The Huvitz Fundus camera has the following features:

- Auto shoot-image is optimized and captured automatically when aligned and focused to the patient's eye properly.
- Auto tracking-alignment and focus is automatically accomplished in tracking region.
- Pupil mode- Normal mode is 4.0mm, Small pupil mode is 3.3 mm.
- Capture mode- Single Macular mode provides capturing one fundus image for macular. Single Disc mode provides capturing one fundus image for Optic Disc. Widefield-Panorama mode provides the stitching function for maximum 7 adjacent images captured individually.
- 12 inch, color and touch screen provides high quality images and easy to operate GUI available to the operator.
- HUVITZ-Webviewer software of the Server-Client structure exchanges clinical image data with the software built-into HUVITZ'S ophthalmic devices. Images filmed on the device are transmitted to the server and the user can view the image data from any personal PC through web browser without installing additional software. HUVITZ-Webviewer is compatible with Internet Explorer, Chrome, Safari and Firefox.
- HFC-1 Fundus Camara transfers image data to a server in dicom environment.

Description:

HFC-1 Fundus Camera captures, store and display color fundus images with built-in 20 Mega pixel colored channel up to 45-degree field of view. HFC-1 Fundus Camera is designed as a non-contact, non-invasive and high resolution digital imaging device. HFC-1 Fundus Camera has a retinal imaging system that provides digital images of the eyes to assist physicians in diagnostic examinations. The anterior of an eye is illuminated by IR light, the retina of an eye is illuminated by a white LED, emitted by the fundus illumination optical system. The fundus observation/photography optical system obtains an image with image sensors and images are observed and manipulated on the display panel.

The dimension of HFC-1 Fundus Camera is 330(W) x 542(D) x 521(H) mm. It weights about 28kg. The size of touch screen is 12.1 inch- touch panel color LCD with 1280 x 800 pixel. The user captures an image by pressing the button on the joystick. At the bottom of the device, there are USB, LAN and DP port to store, retrieve and share digital image data in a network environment.

Safety:

All necessary safety testing was conducted on the subject device and demonstrated that HFC-1 is substantially equivalent to the predicate device in terms of safety and effectiveness. The safety testing included the followings:

1. Electrical and Mechanical Safety Testing (according to IEC 60601-1)

2. Electromagnetic Compatibility (according to IEC 60601-1-2)

3. Light Hazard Testing (according to IEC 15004-2)

4. Disinfection (tests according to ISO 10993-1)

   Cross-disinfection is informed in the user manual, so users are able to avoid risks.

5. ANSI Z80.36-2016

   American National Standard for Ophthalmics - Light Hazard Protection for Ophthalmic Instruments

Effectiveness:

Concerning the validation of effectiveness of HFC-1 Fundus Camera, HFC-1 Fundus Camera has been tested in comparison with the predicate device according to the requirements of ISO 10940:2009 (Ophthalmic Instruments-Fundus Cameras) and it demonstrated a similar image quality to the predicate device. Furthermore, the subject device has same technical features with its predicate device with regard to resolving power, tolerance of angular field of view and range of focus. Also, the performance test shows that HFC-1 Fundus Camera corresponds to all the specifications described in the manual.

1. Summary of Performance Test

Test list	Test standard	Pass or Fail Criteria	Test result
Resolution	①Center: 60 line pairs / mm or more ②Middle: more than 40 line pairs / mm ③Around: 25 line pairs / mm or more Instrument and Jig Control #: W2AUAA-17-00055, P-205, P-223	The Pass or Fail Criteria for Resolution is established based on ISO 10940 Standard. After HFC-1 focused on the USAF chart located 1 m from the pupil and took a picture, the chart displayed on the LCD monitor was judged by being read.	Center: 62 (6G3E) 70.23(-1G6E) Middle: 41 (6G2E) 62.59(-1G5E) Around: 28 (6G1E) 39.41(-1G1E) ■P, □F
Image Capture Angle	45˚ ± 5% (normal mode) 42.75˚~47.25˚ (787.0~869.8) Instrument and Jig Control #: W2AUAA-17-00054, P-205, P-223	The Pass or Fail Criteria for Image Capture Angle is established based on ISO 10940 Standard. After photographing the scale at a distance of 1m away from the pupil, divide the photographed distance by 2 to calculate r in mm. Calculated by the following formula: Field of View – 2 * arctan (r/1000) Because image capture angle of	43.1 ˚ ⌀ (790) r 395 ■P, □F

		HFC-1 fell within the given range, HFC-1 passed the test.	
Pupil diameter	① 4.0 mm or more (normal mode) Instrument and Jig Control #: W2AUAA-17-00043	Because Minimum Pupil Diameter for HFC-1 is 4.0mm on Normal Mode, the test should verify that HFC-1 has more than 4.0mm pupil diameter. After setting to normal mode, HFC-1 took a shot of model eye which had 4.0mm pupil diameter. Because it was possible for HFC-1 to take a shot of the model eye whose pupil diameter was 4.0mm, HFC-1 passed the test.	■P, □F
	② 3.3 mm or more (Minimum pupil measurement mode) Instrument and Jig Control #: W2AUAA-17-00064	Because Minimum Pupil Diameter for HFC-1 is 3.3mm on Minimum Pupil Measurement Mode, the test should verify that HFC-1 has more than 3.3mm pupil diameter. After setting to Minimum pupil measurement mode, HFC-1 took a shot of model eye which had 3.3mm pupil diameter. Because HFC-1 could take a shot of the model eye whose pupil diameter was 3.3mm, HFC-1 passed the test.	■P, □F
Pixel pitch of sensor in fundus	3.69um ± 7% (3.4317 ~ 3.9483) Instrument and Jig Control #: W2AUAA-17-00054	According to ISO 10940, tolerance of pixel pitch on fundus is ± 7 %. After taking a shot of 100mm scale located 1 m away, use Device Calibrator Software	3.53 um
Light intensity control	Step 10 should be	Because HFC-1 has light intensity level from 1 to 10, the test attempted to verify that each level of light intensity was well-operated and well-controlled.	■P, □F

		Since each level of light intensity for HFC-1 was well-operated and well-controlled, HFC-1 passed the test.	
Objective lens reflected light and black spot	The difference between the circumference and 10 should be less.	The test standard is established considering Huvitz senior engineer and researcher's opinion. Because the result met the test standard, HFC-1 passed the test.	■P, □F
Working Distance	Capture fundus image: 33mm± 1mm Instrument and Jig Control #: P-204, P-241	After installing model eye with 4.0mm aperture on the chinrest, move the body with a joystick in fundus shooting mode to align and focus. The distance from the objective lens to the model is measured with a ruler. Because the result met the test standard, HFC-1 passed the test.	■P, □F
Diopter adjustment range	Total: -33D ~ + 33D to be adjusted ①Without correction lens: -13D ~ + 13D should be adjusted ②+ Corrected lens entrance: + 7D ~ + 33D ③- When the compensation lens is charged: -33D ~ -7D should be adjusted Instrument and Jig Control # : W2AUAA-17-00032, W2AUAA-17-00034, W2AUAA-17-00035, W2AUAA-17-00039, W2AUAA-17-00040, W2AUAA-17-00063,	After selecting the corrective lens by pressing C.lens icon, mount the model eye corresponding to the minimum / maximum range of the correction lens on the chinrest. Move the focus lens to a position in the maximum/minimum range. Use the joystick to align and focus the body, then shoot an image. Check if the captured image is clear, then record the result. Since	■P, □F
Moving range	Body front and back: 70mm ± 5mm Body right and left: 100mm ± 5mm Body top and bottom: 30mm ±5mm Instrument and Jig Control #: P-204 P-241	Move the body in direction of where you want to measure with the joystick then move the body in the opposite direction. Use the ruler to measure moving distance. Since moving distance in each direction met the test standard, HFC-1 passed the test.	Front Back: 70 mm Left Right: 102 mm Up down: 30.5 mm ■P, □F

	Top and bottom of chin rest: 62mm ± 5mm Instrument and Jig Control #: P-204 P-241	Press Chinrest Button and move the chinrest to the top or bottom. Then, move the chinrest in the opposite direction. Then measure the distance with the ruler. Since Chinrest moving distance in each direction met the test standard, HFC-1 passed the test.	Up down: 65 mm ■P, □F
Auto Tracking	Top and Bottom: 30mm ±1mm Right and Left: 10mm ±1mm Front and Rear: 10mm ±1mm Instrument and Jig Control #: P-204, P-241	Turn off Auto Tracking Function. After the model eye is mounted on the chinrest, align and focus. Use the joystick to move the body until the limit mark appears in the direction you want to measure. Place the ruler on the body. Turn on the Auto Tracking function, move the body in the opposite direction until the limit mark appears, and then measure the distance traveled. Because HFC-1 met the test standard, HFC-1 passed the test.	Top and Bottom: 30 mm Right Left: 11 mm Front Back: 10 mm ■P, □F
Sleep mode	5 Min ±5 Sec	The test standard is established considering Huvitz senior engineer and researcher's opinion. Because the result met the test standard, HFC-1 passed the test.	■P, □F
LCD Tilting Angle	70° ± 5% (66.5~73.5) Instrument and Jig Control #: P-207	The test standard is established considering Huvitz senior engineer and researcher's opinion. Because the result met the test standard, HFC-1 passed the test.	Angle 71 ° ■P, □F
Cornea Flare	The ring of light is located at the center of the mask. Equal width and upper and lower, left, right sides should be constant when rotated (2nd step) Instrument and Jig Control #: W2AUAA-17-00021	The test standard is established considering Huvitz senior engineer and researcher's opinion. Because the result met the test standard, HFC-1 passed the test.	■P, □F

Lens Flare	The ring of light is located at the center of the mask. Equal width and upper and lower, left, right sides should be constant when rotated (3rd step) Instrument and Jig Control #: W2AUAA-17-00021	The test standard is established considering Huvitz senior engineer and researcher's opinion. Because the result met the test standard, HFC-1 passed the test.	■P, □F

2. Image Quality Comparison Tests

The images from the predicate device and the HFC-1 were shown to the physician for comparison in image quality.

The result was supportive of equivalence of HFC-1 to the predicate device with regard to image quality. The test report can be found in Performance Testing: Bench folder.

3. HFC-1 Performance Test in Resolving, Field of View and Panorama Function

This testing measures resolving power and field of view of HFC-1 compared to HFC-1. Based on the result, HFC-1 is as effective as AFC-330. Also, the test demonstrates that HFC-1 has panorama function like AFC-330. The test report can be found in Performance Testing: Bench folder.

Substantial equivalence:

According to the detailed substantial equivalence comparison between HFC-1 and AFC-330, HFC-1 is equivalent with regards to intended use, technological and biological function, and clinical performance to AFC-330 from Nidek. However, HFC-1 uses the different design and materials from AFC-330 which do not have any effects on HFC-1's clinical function and characteristics.

- Technical/Clinical/ Biological Characteristics Similarities:

- Technical Similarities: Type of Photography, Angle for view, Observable/photographable diameter of pupil, Principle Operation, Conditions of Use

- Clinical Similarities: Indication for Use, Intended Use, Site in the body, Intended Patient Population, User profile

- Biological Similarities: Parts of the body contacted by the device

- Technical/Clinical/Biological Characteristics Differences:

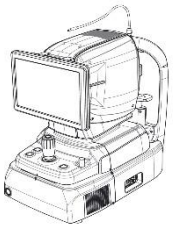
- Technical Differences: Design, Dimension, Operating Distance, Measurable range of dioptric power for the patient's eye in case without the diopter compensation lens and when the convex compensation lens is used, LED Light Source, Base Movement, Power specification for system main body.

- Clinical Differences: found no differences
- Biological Differences: found no differences
- Critical Performance Characteristics Similarities:

-Performance Characteristics: Fundus Image Resolution.

- HFC-1 and AFC-330 have the same Fundus Image Resolution

- **Comparison of features and specifications of the predicate devices and subject devices**

Characteristic	**Predicate Device** Non-Mydriatic Auto Fundus Camera AFC-330	**Subject Device** Huvitz Fundus Camera HFC-1	**Comparison Comments**
510(k) number	K113451	K202097	-
Manufacturer	Nidek Co., Ltd	Huvitz Co.,Ltd	-
Device Name	Non-Mydriatic Auto Fundus Camera AFC-330 with Image Filing Software NAVIS-EX AFC-330	HFC-1 Fundus Camera	-
Design	 LCD, Forehead rest, Chinrest, External LED, Base, Joystick	 LCD, Headrest, Chinrest, External LED, Base, Joystick	Same
Indications for Use	The Non-Mydriatic Auto Eundus Camera AFC-330 with Image Filing Software NAVIS-EX is intended to capture, display, store and manipulate images of the retina and the anterior segment of the eye, to aid in diagnosing or monitoring diseases of the eye that may be observed and photographed.	HFC-1 fundus camera is intended to capture digital images for the anterior and retina segment of the eye without the use of a mydriatic agent. It is intended for use as an aid to clinicians in the evaluation and diagnosis of ocular health.	There is a minor difference in the indications for use statement but the meaning is similar.
Design			
Design & Dimension	AFC-330 is composed of LCD, Forehead rest, Chinrest, External LED, Base, Joystick The dimension of AFC-330 is 316 (W) x 518 (D) x 579 (H) mm	HFC-1 is composed of LCD, Headrest, Chinrest, External LED, Base, Joystick The dimension of HFC-1 330(W) x 542(D) x 521(H) mm	The size of AFC-330 with LCD is smaller than HFC-1 with LCD. These differences are about operator convenience. The interaction with a patient is same. This difference does not raise any new issues of safety or effectiveness
Power Supply	AC 100 - 240V, 50/60Hz, 150VA	AC 100 - 240 V, 50/60 Hz, 1.6 - 0.7 A	HFC-1 is evaluated by IEC60601-1 and meet

Characteristic	Predicate Device Non-Mydriatic Auto Fundus Camera AFC-330	Subject Device Huvitz Fundus Camera HFC-1	Comparison Comments
	for system main body	for system main body	the requirement.
Conditions of Use	Use environment -. Temperature: 10°C to 35°C -. Humidity: 30% to 90% -. Pressure: 800hpa to 1060hpa Storage environment -. Temperature: -10°C to 55°C -. Humidity: 10% to 95% -. Pressure: 700hpa to 1060hpa	Use environment -. Temperature: + 10℃ to + 35℃ -. Humidity: 30% to 90% -. Pressure: 800hPa to 1060hPa Storage environment -. Temperature: - 10℃ to + 55℃ -. Humidity: 10% to 95% -. Pressure: 700hPa to 1060hPa	Exactly the same
Principle Operation (Fundus)	The patient's eye is illuminated by near infrared light, which is emitted by the fundus illumination optical system. The fundus observation/photography optical system forms and image on the image pick-up element(fundus observation camera), and the image cane be observed on the control panel	The anterior of an eye is illuminated by IR light, the retina of an eye is illuminated by an infrared light and a white LED, of which lightings are emitted by the fundus illumination optical system. The fundus observation/photography optical system forms and makes an image with image sensors, which images are observed and manipulated with the display panel.	Exactly the same
Type Of Photography	Color, Red-free& IR	Color, Red-free& IR	Exactly the same
LED Light Source	For observation: Halogen lamp 12V 50W For capturing: Xenon flash lamp 300Ws	Max 50Vdc, 120 mW	The power of LED light source of HFC-1 is lower than the model AFC-330. The LED is used to illuminate patient's eye. The photo biological safety is tested and evaluated by manufacturer of LED according to IEC 62471. The performance results meets the requirement of ISO10940. LED light is much brighter than halogen bulbs of the same wattage. The energy output of AFC-330 is larger than

Characteristic	Predicate Device Non-Mydriatic Auto Fundus Camera AFC-330	Subject Device Huvitz Fundus Camera HFC-1	Comparison Comments
			HFC-1 but HFC-1 can be as bright as Halogen bulb and last longer.
Material of contact parts	Forehead rest: Silicone rubber Chinrest: Acrylonitrile butadiene styrene resin Chinrest paper pin: Polyamide resin	Headrest rubber: Silicone rubber 1 Chinrest: Acrylonitrile butadiene styrene resin Chin-rest paper: paper	Parts that in contact with patient intact skin is evaluated by ISO10993-5 and ISO 10993-10. The results meet the requirement of Standards.
Performance			
Fundus Image Resolution	Central area: 60 lines pairs/mm or more Middle area: 40 lines pairs/mm or more Peripheral area: 25 lines pairs/mm or more	Center: 60 lines/mm or more Middle (r/2): 40 lines/mm or more Middle (r) : 25 lines/mm or more	Exactly the same
Angle for View (Field of View)	45° (33° in Small pupil photography mode) According to the bench test, FOV of AFC-330 was 43. 1°	45° According to the bench test, FOV of HFC-1 was 43.6°	Difference in Angle for View between HFC-1 and AFC-330 was really small which indicates that there would be no significant effect on Fundus Camera performance.
Observable / Photographable Diameter of Pupil	Normal pupil diameter: Φ4.0mm or more Small pupil diameter: Φ3.3mm or more	Normal pupil diameter: Φ4.0mm or more Small pupil diameter: Φ3.3mm or more	Exactly the same
Operating Distance (Working Distance)	45.7 mm	33 mm	Operating distance is different for the subject and predicate device according to their internal structure. All performance outcomes meet the requirement of ISO10940.

Characteristic	Predicate Device Non-Mydriatic Auto Fundus Camera AFC-330	Subject Device Huvitz Fundus Camera HFC-1	Comparison Comments
			The shorter the working distance, the smaller the objective lens size. This makes it easy to fabricate and reduces the manufacturing costs. Also, since the overall size becomes smaller, it can be manufactured into a compact design structure.
Measurable range of dioptric power for the patient's eye	Total Measureable Range: -33D to +35D	Total Measurable Range: -33D ~ +33D	Overall measurable range of dioptric power for the patient's eye is very similar between the model AFC-330 and HFC-1. Actually measurable range was led by +/- compensation lens which made by different lens processing technology depending on each manufacturer. All requirement of performance meets the requirement of ISO10940.
	Without the diopter compensation lens: -12D to +15D	Without the diopter compensation lens: -13D ~ +13D	
	When the convex compensation lens is used: +11D to +35D	When the convex compensation lens is used: +7D ~ +33D	
	When the concave compensation lens is used: -33D to -7D	When the concave compensation lens is used: -33D ~ -7D	Exactly the same
Base Movement	Back-and-forth 40mm, Right-and-left 85mm	Back-and-forth 70mm, Right-and-left 100mm	The range of movement of HFC-1 is wider than AFC-330 excluding op/down movement. The range of movement is sufficient to align between device and patient.
Base up and down movement	32mm	30mm	
Chin-rest movement	62mm	62mm	Exactly the same
Auto Tracking Range	32 mm (up and down), 10 mm (right and left), 10 mm (back and forth)	30mm (up and down), 10mm (right and left), 10mm (back and forth)	The performance of auto tracking range of HFC-1 is wider than AFC-330. does not affect safety.

Summary of Performance Test

- Performance testing including biocompatibility, service life, functional and mechanical testing and transportation were conducted in accordance with standards. Animal and clinical data were not submitted. Performance testing demonstrated that the device meets all the specific requirements and performs as intended.

Conclusion

- The device is substantially equivalent to the predicate device according to the comparison of intended use, indications for use, technological and clinical characteristics. HFC-1 fundus camera has the same resolving power as the predicate device which means that HFC-1 can produce the similar quality images as its predicate device, AFC-330. The sponsor believes that HFC-1 fundus camera is as safe and effective as the identified predicate devices. Any new issues of safety and effectiveness are not found. Therefore, HFC-1 fundus camera, the subject device, is substantially equivalent to AVC-330, the predicate device.