October 27, 2026

Robotrak Technologies Co., Ltd.
Jie Zhang
Official Correspondent
163 Caversham Woods, Pittsford
Pittsford, New York 14534

Re: K261740
Trade/Device Name: Adaptive Optics Scanning Laser Ophthalmoscope (Mona IV)
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: MYC
Dated: September 18, 2026
Received: September 18, 2026

Dear Jie Zhang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

BENNETT N. WALKER -S

Digitally signed by BENNETT N. WALKER -S
Date: 2026.10.27 12:47:50 -04'00'

for CAPT Bradley Cunningham, MSE, RAC
Acting Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K261740

Device Name
Mona IV

Indications for Use *(Describe)*
The Mona IV is a non-contact ophthalmic diagnostic imaging device. It is an infrared scanning ophthalmoscope intended for two dimensional, high resolution imaging of the posterior segment of the eye. The device utilizes Adaptive Optics (AO) technology to compensate for ocular aberrations, enhance spatial resolution to facilitate the visualization of photoreceptors and retinal vasculature.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Device Common Name:	Adaptive Optics Scanning Laser Ophthalmoscope
Trade Name:	Mona IV
Model/Type reference：	Mona IV
Type of submission:	Traditional
Date of preparation:	October 27, 2026
Manufacturer:	Robotrak Technologies Co., Ltd. 1F, Building 2, No.6 Qiande Rd, Jiangning District,Nanjing, Jiangsu 210000，China
Submitter and contact:	Ms. Li Zhang Robotrak Technologies Co., Ltd. Regulatory Affairs Manager 1F, Building 2, No.6 Qiande Rd, Jiangning District,Nanjing, Jiangsu 210000，China Phone: +86-25-58506373 Fax: +86-25-58506373 Email: li.zhang@robotrak.cn
Product Code:	MYC
Regulation Number:	886.1570
Common Name:	Ophthalmoscope
Panel:	Ophthalmic
Class:	Class II
Indications for Use:	The Mona IV is a non-contact ophthalmic diagnostic imaging device. It is an infrared scanning ophthalmoscope intended for two dimensional, high resolution imaging of the posterior segment of the eye. The device utilizes Adaptive Optics (AO) technology to compensate for ocular aberrations, enhance spatial resolution to facilitate the visualization of photoreceptors and retinal vasculature.

Predicate device:	Eidon Fa, Eidon, Eidon Af, Eidon Uwfl (K211328)
ProductCode:	MYC
Regulation Number:	886.1570
Common Name:	Ophthalmoscope
Panel:	Ophthalmic
Class:	Class II

● Device Description

The Mona IV is a dual-channel ophthalmic imaging system designed to provide high-resolution cellular-level Adaptive Optics Scanning Laser Ophthalmoscope imaging with simultaneous Wide-Field Scanning Laser Ophthalmoscope as an auxiliary channel. To achieve its intended use, the device hardware architecture is divided into three interdependent modules:

1.The AOSLO (Adaptive Optics Scanning Laser Ophthalmoscope) Module: Serves as the high-resolution imaging subsystem, utilizing dynamic wavefront sensing and correction to achieve diffraction-limited imaging of a small patch of targeted retinal region.

2.The WFSLO (Wide-Field Scanning Laser Ophthalmoscope) Module: Serves as a low-resolution macula navigation and alignment subsystem, providing wide-field retinal imaging for ROI selection, pupil alignment, and fixation target.

3.The Computing and Processing Module: Serves as the central control hub, executing real-time hardware synchronization, closed-loop adaptive optics calculations, image processing and data storage.

● Working Principle of AOSLO

Mona IV's AOSLO module illuminates a small patch of subject's retina with an infrared flying beam spot and records the retina's back-scattered light and multi-scattered light with detectors, forming images of the illuminated patch. The imaging technique, non-invasive and non-contact, is commonly referred as Scanning Laser Ophthalmoscope (SLO), providing two dimensional image with minimal optical radiation to the patient's eye.

Traditional retinal imaging devices' image quality is commonly limited by human eye aberration, not by the quality of the camera optics. In AOSLO, besides the SLO part, the module is also combined with an Adaptive Optics (AO) sub-module inside, which includes a wavefront sensor and a wavefront corrector. The AO part works simultaneously, but independently from the SLO part. The wavefront sensor is designed to measure the subject eye's wavefront aberration and the wavefront corrector immediately corrects that aberration in real-time close-loop manner, thus greatly enhancing the imaging resolution to visualize cellular level details of the retina.

● Comparison Between the Subject and the Predicate Device

Mona IV and EIDON both supports infrared imaging, Mona IV does not have a fluoroscopy function (the only difference is that Mona IV does not have a fluoroscopy function).

Item	Subject Device K261740	Predicate Device K211328	Same / Similar or Different
Indications for Use	The Mona IV is a non-contact ophthalmic diagnostic imaging device. It is an infrared scanning ophthalmoscope intended for two dimensional, high resolution imaging of the posterior segment of the eye. The device utilizes Adaptive Optics (AO) technology to compensate for ocular aberrations, enhance spatial resolution to facilitate the visualization of photoreceptors and retinal vasculature.	The CenterVue EIDON FA is a confocal scanning ophthalmoscope indicated for color, infrared and auto fluorescence imaging and fluorescein angiography of a human retina with or without the use of a mydriatic agent.	Similar

General Device Description	The Robotrak Mona IV is a confocal scanning ophthalmoscope which uses infrared light to obtain confocal images of the retina.	The CenterVue EIDON is a confocal scanning ophthalmoscope indicated for color, infrared and auto fluorescence imaging and fluorescein angiography of a human retina.	Similar
Class and type of applied part	Class I, Type B (according to IEC 60601-1).	Class I, Type B (according to IEC 60601-1).	Same
Sensor digital resolution (AOSLO)	1024 x 1024	14 Mpixel (4608x3288)	Different Sensor digital resolution of subject device is sufficient to sample key retinal structures. Difference does not affect the safety and effectiveness of the device and does not represent a new intended use.
Sensor digital resolution (WFSLO)	512 x 512		
Digital resolution on retina (AOSLO)	853 pixel/deg in 1.2° FOV 427 pixel/deg in 2.4° FOV 205pixel/deg in 5° FOV	60 pixels/deg (centre of the field) 45 pixels/deg (centre of the field), with Ultra Widefield Lens	Different Digital resolution on retina of subject device is higher and sufficient to sample key retinal structures. Difference does not affect the safety and effectiveness of the device and does not represent a new intended use.
Digital resolution on retina (WFSLO)	14.2 pixel/deg		
Optical resolution on retina (AOSLO)	2.2microns in 1.2° FOV 2.2microns in 2.4° FOV 3.1microns in 5° FOV	15 microns 17 microns, with Ultra Widefield Lens	Different Optical resolution on retina of subject device is better and sufficient to sample key retinal structures. Difference does not affect the safety and effectiveness of the device and does not represent a new intended use.
Optical resolution on retina(WFSLO)	40microns		
Field of view(AOSLO)	1.2° (H) x 1.2° (V) 2.4° (H) x 2.4° (V) 5° (H) x 5° (V)	60° (H) x 55° (V) captured in a single exposure 80° (H) x 75° (V) captured in a single exposure, with Ultra Widefield Lens	Different FOV on retina of subject device is sufficient to image macular area. Difference does not affect the safety and effectiveness of the device and does not represent a new intended use.
Field of view(WFSLO)	36° (H) x 28° (V)		

Pixel pitch(AOSLO)	0.34microns in 1.2° FOV 0.7microns in 2.4° FOV 1.4microns in 5° FOV	4.9 microns 6.34 microns, with Ultra Widefield Lens	Different Pixel pitch on retina of subject device is higher and sufficient to sample key retinal structures. Difference does not affect the safety and effectiveness of the device and does not represent a new intended use.
Pixel pitch(WFSLO)	20microns		
Range of focus	-10D to +4D	-12 D to +15 D -8 D to +8 D with Ultra Widefield Lens	Similar
Minimum pupil size	4mm	2.5 mm (non-mydriatic use)	Similar
Light sources	infrared SLED (820-880nm) infrared SLED (760-800nm) infrared LED (940nm)	infrared LED (825-870 nm), white LED (440-650 nm), blue LED (440-475nm) a green LED	Similar
Imaging modalities	IR reflectance and IR phase contrast	color, red-free, IR reflectance, autofluorescence (AF), fluorescein angiography (FA)	Different
Working distance	>30mm	28 mm 16 mm, with Ultra Widefield Lens	Similar
Automatic operation	Semi-auto alignment, auto-focus, auto-exposure, manual capture	auto-alignment, auto-focus, auto-exposure, auto-capture	Similar
Internal fixation target	dynamic, programmable	dynamic, programmable	Same
Adaptive optics technology	Support	/	Different
Weight	45 Kg±2Kg	25 Kg (55 lbs)	Different
Size (W x H x D)	550mm x 690mm x600mm	620mm x 590mm x360mm (14.2” x 23.2” x 24.4”)	Different
Voltage Power consumption	AC 100-240V； <500W	12 V DC; 60 W	Different
Interface	Ethernet Interface: connect the printer via the TCP/IP transmission protocol. USB 3.0 Interface: connect mouse and keyboard to the device via the USB 3.0 protocol. DP Interface: connect auxiliary devices such as monitors via the DP interface protocol.	USB support	Similar

Biocompatibility	ISO 10993	ISO 10993	Same
Electrical Safety	IEC 60601	IEC 60601	Same
Laser Safety	IEC 60825-1、ANSIZ80-36 ISO15004-1、ISO15004-2	ANSIZ80-36	Same
Software	IEC62304	IEC62304	Same
Performance	/	ISO 10940	Different

Different – Sensor digital resolution

Sensor resolution is a parameter specific to imaging hardware; both products utilize medical-grade digital sensors that comply with hardware safety standards for ophthalmic imaging equipment. The sensor resolution of the declared product is optimized for its 5° field of view imaging design, fully meets the clarity requirements for retinal infrared imaging, and has passed comprehensive performance validation for retinal resolution and optical resolution. This difference is solely a parameter related to the adaptability of the digital sensor; it does not alter the imaging principle or core clinical applications, nor does it introduce new risks to electrical safety or imaging performance. Therefore, it will not adversely affect the safety or effectiveness of the product.

Different - Digital resolution on retina

Retinal resolution (pixels/deg) is a performance indicator of imaging clarity; it does not involve safety limit parameters, nor does it alter the device's core operating principles or intended use. This metric solely represents the number of pixels per unit angle and is unrelated to optical radiation, electrical safety, or mechanical safety. The optical path, light source power, and electrical structure of the subject device have all been validated in accordance with medical standards, and no new safety risks have been introduced due to the increased resolution. Higher pixel density does not increase the dose of light exposure to the eye or the risk of injury. The subject device's 205 pixels/deg is significantly higher than that of predicate product, resulting in finer imaging and clearer details, which significantly enhances imaging effectiveness. This metric meets and exceeds the resolution requirements for clinical retinal infrared imaging, reliably delivering the image quality necessary for clinical diagnosis. Therefore, this difference does not adversely affect the product's safety or effectiveness; rather, it further enhances its clinical utility.

Different - Optical resolution on retina

Optical resolution is a core performance metric for retinal imaging devices. The optical resolution of the subject device is significantly superior to that of the predicate product, enabling clearer imaging of fine retinal structures and directly enhancing the clinical efficacy of infrared imaging. This parameter design strictly complies with the ANSI Z80.36 standard for optical safety of ophthalmic instruments. All optical designs have undergone photobiological safety validation, and no new optical radiation risks have been introduced. The improved resolution merely enhances the product's imaging performance without altering its core intended use or operating principles. Therefore, this difference will not adversely affect the product's safety or effectiveness; rather, it further enhances its clinical efficacy.

Different - Field of view

Field of view is a design parameter for the imaging field. The narrower field of view of the subject device is designed to align with its high-resolution fundus imaging capabilities, better meeting the needs of fine retinal structure observation compared to the wide-area, low-resolution imaging of the predicate products; however, the core application of retinal infrared imaging remains entirely consistent. The field of view design of the subject device has undergone optical performance and safety validation, complies with relevant standards for ophthalmic devices, introduces no new optical safety risks, and, when combined with image stitching post-processing capabilities, the subject device can also meet clinical requirements for wide-field imaging. This difference is solely a design adaptation of the imaging field of view and does not alter the product's core operating principles or intended use; therefore, it will not adversely affect the product's safety or effectiveness.

Different - Pixel pitch
The pixel pitch is designed to match the sensor resolution and optical resolution. The smaller pixel pitch of the subject device aligns with its optical path design featuring high optical resolution, enabling higher detail reproduction in imaging and further enhancing imaging performance. This hardware selection complies with safety standards for medical electrical equipment and has undergone comprehensive electrical safety and performance validation. It introduces no new safety risks and does not alter the product's core imaging principles or intended use; therefore, this difference will not adversely affect the product's safety or effectiveness.

- **Performance Testing**

Testing and validation for optical resolution, field of view, AO correction stability, AO loop rate, optical co-alignment between the AO and wide-field views, and length and area measurement tool, has been conducted and submitted.

Software documentation was provided, and software verification and validation were conducted as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions."

Documentation regarding cybersecurity was submitted as recommended by FDA's Guidance for Industry and FDA Staff, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions".

Documentation regarding cybersecurity was submitted as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" and an overall risk assessment regarding security and safety of the device was conducted due to ISO 14971:2019.

Tests for electrical safety (IEC60601-1:2005+A1:2012+A2:2020) and electromagnetic compatibility (IEC 60601-1-2:2014+A1:2020 and IEC TR 60601-4-2: 2016) were performed with the Mona IV device and passed the relevant requirements of the applied standards.

This device complies with the ISO 15004-1:2020 and ISO 15004-2:2024 standards for ophthalmic instruments, and with the ANSI Z80.36-2021 standard for light hazard protection.

The chin rest and forehead rest components of this product that come into direct contact with the skin are made of polypropylene (PP). In accordance with relevant regulations of the U.S. Food and Drug Administration (FDA) and in reference to the international standard ISO 10993-1, "Biological Evaluation of Medical Devices — Part 1: Evaluation and Testing within a Risk Management Process," the following has been confirmed through risk assessment: 1) The chin rest and forehead rest of this device come into contact with the skin through short-term, non-invasive direct contact with intact skin; 2) The polypropylene (PP) material used is a well-established medical-grade material with a clear history of biocompatibility safety and no known potential biological hazards; 3) Based on the results of the aforementioned risk assessment, the skin-contact materials of the chin and forehead support components of this device meet the criteria for exemption from the three biological tests (sensitization, irritation, and cytotoxicity), and therefore, such tests are not required.

Visualization of photoreceptors and retinal vasculature has been demonstrated in healthy human using subject device in a two center, GCP regulated clinical study (NCT06173414) enrolling 194 adult subjects.
Subjects were excluded if significant ocular media opacity (e.g., dense cataract, corneal opacity, or severe vitreous opacity) or if subject cannot maintain stable fixation or cooperate during imaging (e.g., severe

nystagmus or inability to remain steady) or if photosensitive epilepsy is observed.
After pupil dilation, images of the retinal photoreceptor layer and retinal vasculature were acquired using the system and independently evaluated by two retinal specialists under masked condition. Images were classified as excellent, good or poor. The overall proportion of images rated excellent or good was 86.28% in the full analysis set (FAS) and 86.14% in the per-protocol set (PPS), demonstrating feasibility of clinical imaging of fine retinal structures.
The clinical safety of the system was also evaluated in this study. No serious adverse events (SAEs), resulting in death or study withdrawal, or device-related treatment emergent adverse events（TEAEs）were reported. Visual acuity, intraocular pressure, slit-lamp examination, optical coherence tomography (OCT), and multifocal electroretinography examinations were conducted on subject after subject device imaging, finding NO observable safety concerns.

- **Conclusion**

Based on the information contained within this submission, it is concluded that Mona IV is substantially equivalent to the identified predicate device~~s~~, and that any differences that do exist have no substantial effect on the safety and effectiveness of the device.