March 17, 2025

Centervue Spa
Luca Scienza
Quality Manager
via San Marco 9h
Padova, IT 35129
Italy

Re: K243504
Trade/Device Name: Maia (ahmacme001)
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: MYC
Dated: February 7, 2025
Received: February 11, 2025

Dear Luca Scienza:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Elvin Y. Ng -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243504

Device Name
MAIA (AHMACME001)

Indications for Use *(Describe)*
MAIA is intended for taking digital images of a human retina without the use of a mydriatic agent.

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.

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510(k) Summary in accordance with 21 CFR 807.92

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510(k) Summary

Proprietary Name(s):	MAIA
Type of submission:	Traditional
Date of submission:	March 14th, 2025
Manufacturer:	CENTERVUE S.p.A. Via San Marco 9H 35129 Padova – ITALY
Applicant and contacts:	Mr. Luca Scienza Centervue S.p.A. Manager of Quality and Regulatory Affairs Via San Marco 9H, 35129 Padova - ITALY Phone: +39 049 501 8399 Fax: +39 049 501 8398 Email: luca.scienza@icare-world.com
Product Code(s):	MYC
Regulation Number:	886.1570
Common Name:	Ophthalmoscope
Panel:	Ophthalmic
Class:	Class II
Indications for Use:	MAIA is intended for taking digital images of a human retina without the use of a mydriatic agent.
Predicate Device:	K150320, COMPASS, Product code MYC This predicate has not been subject to a design-related recall

Device description

MAIA is intended for taking digital images of a human retina without the use of a mydriatic agent.

The device works with a dedicated software application, operates as a standalone unit, integrates a multi-touch display, a push-button and is provided with an external power supply.
MAIA operates in non-mydriatic conditions, i.e. without the need of pharmacological dilation and is intended for prescription use only

The key functional elements of the device are:
- the device base,
- the device optical head,
- the headrest,
- the chinrest,
- the multi-touch display,
- the embedded software,
- patient push-button,
- the power supply and its power cable.

The device acquires confocal retinal images illuminating the retina of the patient's eye, with visible light for imaging purposes and with infrared light for imaging purposes, focusing and retinal tracking.
A specific feature of MAIA is the pupil tracking. The patient's pupils are illuminated and viewed by a different optical system; two cameras track the pupil's movements and allow for automatic alignment of the optical head with the eye position.

From an imaging point of view, an important characteristic of MAIA is that it is a confocal instrument: this means that the illumination of the retina is focused on the same plane of the acquisition (same focus). Compared to traditional imaging, where the entire specimen is flooded evenly in light, a confocal illumination system is able to focus the illuminating light on the same focus plane (conjugate plane) of the acquisition optics.
Another important characteristic of MAIA is the use of white light to illuminate the retina.
The result of the combination of confocal imaging and white light obtained in MAIA is the acquisition of sharp, detailed, naturally colored retinal images.

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review.

For this application, the product has also functions that are not subject to FDA premarket review; FDA assesses those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.
The "other function" of the device is the automatic perimetry (Product Code HPT, 510(K) Exempt), that allows the measurement of retinal threshold sensitivity and the analysis of fixation.

This function consists in projecting light stimuli at different intensities together with a uniform light background; the device records the pressures of the pushbutton by the tested patient when he detects such stimuli, as in Standard Automated Perimetry test.
With its retinal tracking, for all the duration of the exam, MAIA acquires infrared images of the retina and detects its movement, to correct the position for the projection of the stimuli, reducing the positioning error that might occur if the patient has poor fixation stability.

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TECHNICAL SPECIFICATIONS

Class and type of applied part

- Class II, Type B (according to IEC 60601-1).

IP classification:

- IPX0 (according to the degree of protection provided by the enclosure with respect to harmful penetration of particulate matter or water).

Image acquisition:

- Field of view: 60° (diameter) captured in a single exposure
- Sensor size: 5 Mpixel (2592x1944)
- Light source: infrared LED (825-870 nm), white LED (440-655 nm)
- Imaging modalities: TrueColor, Infrared
- Resolution on the retina 17 µm
- Minimum pupil size: 3mm
- Working distance 28mm

Other Functions - PERIMETRY:

- Projection field: 30° (diameter)
- Background Luminance 4 asb, white
- Dynamic range: 0 – 36 dB
- Stimulus size: Goldmann III
- Stimulus shape and color Round, white
- Stimulus duration 200 ms
- Test strategies: 4-2, 4 Levels Fixed, Scotoma Finder, FixationOnly
- Test patterns: Standard 10°, Circular 6°, Circular 20°, 10-2, Custom grids
- Fixation control: 25 Hz automated retinal tracking

Other features

- Automatic operation: Auto-alignment, auto-focus, auto-exposure, auto-capture
- Focus adjustment range: -12 D to +15 D
- Internal fixation target: Internal, multi-point
- Display: 15” multi-touch embedded color display
- Hard disk: SSD, 480 GB or higher
- Network connectivity: 1Gbit Ethernet, 802.11ac/b/g/n Wi-Fi

Dimensions:

- Weight: 27 Kg (59 lbs)
- Size (W x H x D): Device size: 360 x 590 x 620 mm (14.2" x 23.2" x 24.4")
  Display size: 390 x 180 x 190 mm (15.4" x 7.1" x 7.5")

Power supply:

- Voltage: 100-240 VAC, 50-60 HzC
- Power consumption: 80 W

Substantial Equivalence Discussion

Indications of use statements of both the proposed predicate device and the subject device are reported below.

> COMPASS is intended for taking digital images of a human retina without the use of a mydriatic agent and for measuring retinal sensitivity, fixation stability and the locus of fixation. It contains a reference database that is a quantitative tool for the comparison of retinal sensitivity to a database of known normal subjects.
>
> MAIA is intended for taking digital images of a human retina without the use of a mydriatic agent.

For what concerns indications for use, MAIA is substantially equivalent to the predicate device COMPASS. The only differences between the subject device MAIA and the proposed predicate (COMPASS, K150320) are the references to features that are not subject to FDA premarket review.

MAIA is technologically equivalent to the predicate device COMPASS.
MAIA has the same technology as the predicate device COMPASS, including design, materials, and principle of operation. Fundus Perimetry is the technological principle for both the subject and primary predicate device. It is based on continuous imaging of the retina using infrared illumination, to enable compensation of eye movements during exams. At a high level, the subject and primary predicate device are based on the same technological elements.
Indeed, the performance of the fundus imaging function in MAIA can be inferred from the performance data of the COMPASS device, as they are technologically identical.

Based on the non-clinical tests (i.e. bench tests), MAIA is safe and performs as intended when used according to its indications for use and in accordance with its labeling. It performs as well as the legally marketed predicate device COMPASS (K150320).

Bench tests performed and submitted provide complete evidence of safety and performance of MAIA. Notably, the consensus standards used hereby are the same used for the predicate device COMPASS (K150320), apart from the adoption of newer edition, as applicable.

The MAIA device has undergone a series of rigorous tests and validations to ensure that its safety and performance are at least equivalent to the predicated device COMPASS.
Electromagnetic compatibility testing confirmed that the device does not interfere with other electronic equipment and is adequately immune to electromagnetic disturbances.
Basic safety evaluations showed that the device poses no risk of electrical shock, fire, or mechanical hazards.

Functional safety tests verified that the device operates correctly and that any potential faults do not lead to hazardous situations.
Performance testing, based on ISO 15004-1, ANSI Z80.36, ISO 12866 standards, demonstrated that the device meets the specified requirements for ophthalmic instruments.
Usability testing indicated that the device can be used safely and effectively by the intended users under expected use conditions.
Biocompatibility tests, along with the packaging and environmental conditions validations, demonstrated that the device is safe and performs according to its intended use.
The software embedded in the MAIA device was validated according to IEC 62304, ensuring that it meets the requirements for medical device software. Security penetration testing was conducted to identify and mitigate potential cybersecurity vulnerabilities, and labeling validation confirmed that the device provides the necessary information for safe and effective use.
These comprehensive testing and validation activities provide evidence that the MAIA device is as safe as and performs as well as the proposed predicate device COMPASS (K150320).
No clinical tests were needed.

Conclusion

Based on the information contained within this submission, it is concluded that the MAIA is substantially equivalent to the identified predicate device already in interstate commerce within the USA, with a safety and effectiveness profile that is similar to the predicate device.