November 20, 2023

Zilia Inc.
% Christina Henza
Regulatory Consultant
Ultra Life Science Solutions Inc.
2811 Milton Ave #409
Janesville, Wisconsin 53545

Re: K230627
Trade/Device Name: Zilia Ocular FC (ZIL-10002)
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic camera
Regulatory Class: Class II
Product Code: HKI
Dated: October 27, 2023
Received: October 27, 2023

Dear Christina Henza:

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230627

Device Name
Zilia Ocular

Indications for Use *(Describe)*
Zilia Ocular is a non-contact imaging device for capturing, displaying and storing images of the retina under mydriatic conditions.

Zilia Ocular is intended for use as an aid to clinicians in the evaluation and documentation 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.

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510(k) SUMMARY
Zilia Inc.
Zilia Ocular Fundus Camera (Zilia Ocular FC)

This 510(k) summary is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92.

SUBMITTER	
Company Name	Zilia Inc.
Company Address	125 Charest Boulevard East, Suite 400 Quebec City, Quebec, Canada G1K 3G5
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Date prepared	2023-10-10

DEVICE INFORMATION	
Trade Name	Zilia Ocular Fundus Camera
Common Name	Zilia Ocular FC
Classification Name	Ophthalmic Camera, AC powered
510(k) Number	K230627
Regulatory Class	Class II

Product Code	HKI
Regulation Number	21 CFR 886.1120

PREDICATE DEVICE	
Trade Name	NFC-700 Non-Mydriatic Auto Fundus Camera
Classification Name	Ophthalmic Camera, AC powered
510(k) Number	K182199

REFERENCE DEVICE	
Trade Name	Mydriatic Hyperspectral Retinal Camera (MHRC-C1)
Classification Name	Ophthalmic Camera, AC powered
510(k) Number	K200254

DEVICE DESCRIPTION

The Zilia Ocular Fundus Camera (Zilia Ocular FC) is a non-contact, stand-alone device designed to image the eye fundus.

The device includes a base, a head support, an onboard computer with a 15.6" touch-screen display and an optical head. A joystick, situated at the base of the device, controls the movements of the optical head to enable adequate positioning. The touch-screen display also includes a user interface allowing the user to control the device and acquire and display patient data and images.

The Zilia Ocular FC uses near-infrared (NIR) light-emitting diodes (LEDs) as illumination during alignment to the patient's pupil, and a white LED during focusing and imaging of the eye fundus. The region of the eye fundus being imaged can be modified by changing or moving the fixation target. The images are saved and stored on the onboard computer.

The dimensions of the Zilia Ocular FC are 620 mm (L) by 360 mm (W) by 500 mm (H) and it weighs about 32 kg.

The detailed technological characteristics and specifications of the Zilia Ocular FC are listed in the section *Comparison Of Technological Characteristics With The Predicate Device* located on page 6 of this summary.

INDICATIONS FOR USE

The Zilia Ocular FC is a non-contact imaging device for capturing, displaying, and storing images of the eye fundus under mydriatic conditions.

The Zilia Ocular FC is intended for use as an aid to clinicians in the evaluation and documentation of ocular health.

PERFORMANCE TESTING

All necessary performance testing was conducted on the Zilia Ocular FC and demonstrated that the subject device is substantially equivalent to the predicate device, the NFC-700, in terms of safety and effectiveness.

Electrical Safety and Electromagnetic Compatibility

It was verified that the Zilia Ocular FC complies with the standard ANSI/AAMI ES60601-1:2005/(R)2012+A1:2012 for electrical safety and with the standard IEC 60601-1-2:2014 for electromagnetic compatibility under the ASCA pilot program.

Recognized Consensus Standards For Ophthalmic Cameras

The Zilia Ocular FC was found to comply with the following recognized consensus standards:

- ISO 15004-1:2020 Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments;
- ISO 15004-2:2007 Ophthalmic instruments - Fundamental requirements and test methods - Part 2: Light hazard protection;
- ANSI Z80.36-2021 American National Standard: Ophthalmics - Light Hazard Protection for Ophthalmic Instruments;
- ISO 10940:2009 Ophthalmic instruments - Fundus cameras; and
- IEC 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.

Risk-Based Approach

The risk management report was prepared to document the evaluation and the decisions made and all necessary safety measures in the design and manufacturing of the Zilia Ocular FC. All documentation in accordance with ISO 14971:2019 Medical devices - Application of risk management to medical devices was created including a Risk Management Plan, a Hazard and Risk Analysis, a Production Failure Mode and Effect Analysis (PFMEA), and a Risk Management Report. The risks related to all applicable hazards which were identified for the Zilia Ocular FC have been reduced to the acceptable level by mitigation.

The Zilia Ocular FC is shown to be at least as safe and effective as the predicate device and the inherent risks are believed to be overcome by the benefits of the device use as indicated. Therefore, all residual risks post-mitigation have been deemed acceptable for this design.

Biocompatibility
The intact skin from the chin and forehead of the patient is intended to contact the Zilia Ocular FC for a short period of time. The biocompatibility of the Zilia Ocular FC was assessed in accordance with ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

Processing of Health Care Products
The Zilia Ocular FC Instructions for Use document was assessed to comply with ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices.

Software Evaluation
The Zilia Ocular FC software was evaluated in accordance with IEC 62304:2006/AMD 1:2015 Medical device software — Software life cycle processes. The software for this device is considered to be a "Moderate Level of Concern" since a failure or latent flaw in the software could directly result in minor injury to the patient or user and due to the use of Off-the-shelf Software.

Labeling
The Zilia Ocular labeling was assessed to verify compliance to ISO 15223-1:2021 and ISO 20417:2021 and all applicable local requirements.

Usability
Zilia applied the recommendations from the FDA's guidance Applying human factors and usability engineering to medical device:2016 and IEC 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability:2010+AMD1:2013+AMD2:2020 to maximize the likelihood that the Zilia Ocular FC is safe and effective for the intended users, uses and use environments.

Clinical Performance Data
This section is not applicable because clinical data was not provided for this 510(k) submission.

Animal Studies
This section is not applicable as there is no data related to animal studies for this 510(k) submission.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE AND REFERENCE DEVICE

The proposed Zilia Ocular FC is substantially equivalent to the NFC-700 Non-Mydriatic Auto Fundus Camera (Crystalvue Medical Corporation) cleared in K182199 on 2019-01-02, certain technical differences are supported by the reference device Mydriatic Hyperspectral Retinal Camera (MHRC-C1) cleared in K200254 on 04/27/2020. The proposed indications for use are equivalent to the predicate and reference device, as the three devices are intended to capture, display, and store images of the eye fundus. The technological characteristics of the proposed Zilia Ocular FC encompass the functionalities of the NFC-700 and MHRC-C1.

Feature	Zilia Ocular Fundus Camera (Zilia Ocular FC) (K230627)	NFC-700 (K182199)	MHRC-C1 (K200254)
Regulation number	21 CFR 886.1120	21 CFR 886.1120	21 CFR 886.1120
Product code	HKI	HKI	HKI, NFJ
Regulation name	Ophthalmic Camera	Ophthalmic Camera	Ophthalmic Camera
Regulatory class	Class II	Class II	Class II
Intended Use / Indication for use	Zilia Ocular is a non-contact imaging device for capturing, displaying, and storing images of the eye fundus under mydriatic conditions. Zilia Ocular is intended for use as an aid to clinicians in the evaluation and documentation of ocular health.	NFC-700 is an AC-powered ophthalmic camera to take photographs of the eye and the surrounding area. NFC-700 is a non-contact, high resolution digital imaging device which is suitable for photographing, displaying and storing images of the retina and external areas of the eye to be evaluated under non-mydriatic	The MHRC-C1 is intended to capture images of the retina at multiple wavelengths (colors) under mydriatic conditions.

Feature	Zilia Ocular Fundus Camera (Zilia Ocular FC) (K230627)	NFC-700 (K182199)	MHRC-C1 (K200254)
		conditions. NFC-700 is indicated for in-vivo viewing of the posterior and external area of the eye and the images are intended for use as an aid to clinicians in the evaluation, diagnosis and documentation of ocular health.	
Prescription use	Rx Only	Rx Only	Rx Only
Fundus image	Mydriatic, color image	Non-mydriatic, color image	Mydriatic, monochrome
Record media	Digital	Digital	Digital
Contact areas with the patients	Chin and forehead	Chin and forehead	Chin and forehead
Mean for alignment	Manual positioning	Fully automatic 3D tracking	Manual positioning
Main technology	AC-powered ophthalmic camera on a support frame with: ● A patient chin and forehead rest for patient head	AC-powered ophthalmic camera on a support frame with: ● A patient chin and forehead rest for patient head	AC-powered ophthalmic camera on a support frame with: ● A patient chin and forehead rest for patient head

Feature	Zilia Ocular Fundus Camera (Zilia Ocular FC) (K230627)	NFC-700 (K182199)	MHRC-C1 (K200254)
	placement.	placement.	placement.
	● Visual fixation target for patient to maintain patient's gaze and the pupil's alignment. ● Camera optical head alignment features to allow the user to observe, align, and target the desired image of the patient's eye area. ● NIR lighting during alignment and white LED lighting during focusing and imaging.	● Visual fixation target for patient to maintain patient's gaze and the pupil's alignment. ● Camera optical head alignment features to allow the user to observe, align, and target the desired image of the patient's eye area. ● NIR lighting during alignment and initial observation to not cause pupil constriction.	● Visual fixation target for patient to maintain patient's gaze and the pupil's alignment. ● Camera optical head alignment features to allow the user to observe, align, and target the desired image of the patient's eye area. ● Monochromatic light (700 nm) during alignment.
	● Camera to record the given images provides lighting with mask to illuminate the selected area for the imaging.	● Camera to record the given images provides lighting with mask to illuminate the selected area for the imaging.	● Camera to record the given images provides lighting with mask to illuminate the selected area for the imaging.

Feature	Zilia Ocular Fundus Camera (Zilia Ocular FC) (K230627)	NFC-700 (K182199)	MHRC-C1 (K200254)
	● Software and control user interfaces to operate the device.	● Software and control user interfaces to operate the device.	● Software and control user interfaces to operate device.
Operation Principle	The optical design of the fundus camera is based on the principle of monocular indirect ophthalmoscopy. 1. Fundus observation: Alignment to the pupil is made using two NIR LEDs. Indicators shown on the screen help the user center the device with the pupil. A white LED is used to focus and image the eye fundus.	The optical design of the fundus camera is based on the principle of monocular indirect ophthalmoscopy. 1. Fundus observation: A built-in light ray from the infrared light LED source to illuminate the fundus. Alignment of the device is performed by built-in eye tracking indicator and working distance indicator to automatically adjust the system to the best XYZ position automatically.	The optical design of fundus camera is based on the principle of monocular indirect ophthalmoscopy. 1. Fundus observation: A positioning system is used to align the camera relative to the patient's eye. Monochromatic light (700 nm) is used during alignment. The fundus is observed through a video feed on an LCD monitor.

Feature	Zilia Ocular Fundus Camera (Zilia Ocular FC) (K230627)	NFC-700 (K182199)	MHRC-C1 (K200254)
	2. Image capture: System uses real-time image analysis to perform image focus adjustment automatically to capture the best quality of image. White light emitted from LEDs irradiates the eye fundus. The light reflected from the eye fundus forms an image, and the image is captured by a built-in color CMOS camera module for fundus image capture.	2. Image capture: System uses split-image technique to do image focus adjustment automatically to capture the best quality of image. White light from LEDs Flash module irradiates the fundus. The light reflected from eye portions forms an image, and the image is captured by a built-in color CMOS camera module for fundus image capture.	2. Image capture: Focus is achieved manually through a focus wheel. System uses a tunable light source that sequentially presents the retina with monochromatic light in the spectral range 905 nm to 450 nm in steps of 5 nm.
Alignment/ visualization light source	Near-infrared LED during pupil alignment White LED during focusing and imaging	Near-infrared LED during alignment White LED during imaging	Monochromatic light (700 nm) during alignment Monochromatic light (sequential from 905 nm to 450 nm in steps of 5 nm) during imaging
Field of view	25°	45°	31.5°

Feature	Zilia Ocular Fundus Camera (Zilia Ocular FC) (K230627)	NFC-700 (K182199)	MHRC-C1 (K200254)
Working distance	55 mm from lens to cornea	25 mm from lens to cornea	46.7 mm from lens to cornea
Minimum pupil diameter	4 mm	4 mm	6 mm
Focus	Manual or automatic	Manual or automatic	Manual
Exposure	Manual	Automatic	Automatic
Compensation for ametropia	-15D to +15D	-15D to + 10D (without compensation lens) -30D to -10D or +5D to +30D (with compensation lens)	-15D to +15D
Internal fixation targets	5 points	10 points	None
External fixation target	1 point, mobile	None	1 point, mobile
Camera resolution - pixel size/pitch	CMOS 5 MP – 3.45 µm (pixel pitch)	CMOS 12 MP – 5.12 µm (pixel pitch)	Not available

Considering the above, the Zilia Ocular FC proposes an equivalent technology and methods as the predicate and reference devices to address the same indications. The noted differences in their detailed specifications do not present any new questions of safety or effectiveness, whereby the devices are substantially equivalent.

CONCLUSION

As described in this 510(k) Summary, comprehensive testing and analysis was conducted on the Zilia Ocular FC to ensure that the device is equivalent to the predicate and reference devices cleared under K182199 and K200254 when used in accordance with its Instructions for Use.

Based on the information in this submission, Zilia Ocular FC has the same intended use, technological characteristics, and operation principles as its predicate and reference devices. Therefore, Zilia Ocular FC is substantially equivalent to the predicate device.