July 31, 2023

Altris, Inc.
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K232088
Trade/Device Name: Altris IMS
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: NFJ
Dated: July 13, 2023
Received: July 13, 2023

Dear Prithul Bom:

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)*

K232088

Device Name

Altris IMS

Indications for Use *(Describe)*

The Altris IMS is a standalone, browser-based software application intended for use by healthcare professionals to import, store, manage, display, analyze and measure data from ophthalmic diagnostic instruments, including patient data, diagnostic data, clinical images and information, reports, and measurement of DICOM-compliant images. The device is also indicated for manual labeling and annotation of retinal OCT scans.

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
Altris, Inc
Altris IMS
7/12/2023

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Altris, Inc. 125 South Clark Street 17th Floor Chicago, Illinois 60603	Regulatory Consultant:	Aclivi, LLC 3250 Brackley Drive Ann Arbor, MI 48105
Telephone:	+1 773 382 8709		+1 (810) 360-9773
Official Contact Email:	Andrey Kuropyatnyk, Director andrey@altris.ai		Chris Brown, Manager acliviconsulting@gmail.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Altris IMS
Classification Name:	System, Image Management, Ophthalmic
Classification Regulations:	21 CFR 892.2050
Device Class:	Class II
Product Code:	NFJ
Review Panel:	Ophthalmic

PREDICATE DEVICE INFORMATION

The Subject device is highly similar in Indications for Use, and technological/design principles to the following legally marketed Predicate device:

510(k)	Predicate Device Name	Company Name
K211715	RetinAI Discovery	RetinAI Medical AG

510(k)	Reference Device Name	Company Name
K170164	3D OCT-1 Maestro	Topcon Corporation

DEVICE DESCRIPTION

Altris IMS is a cloud-based software program to assist healthcare professionals, specifically Eye Care Practitioners (ECPs) with OCT interpretation. Altris IMS utilizes commonly available internet browsers to locally manage and review data which is uploaded to an Amazon AWS cloud-based server. Its intended use is to import, store, manage, display, analyze and measure data from ophthalmic diagnostic instruments, including patient data, diagnostic data, clinical images and information, reports, and measurement of DICOM-compliant images. The platform allows the user to manually annotate areas of interest in the images, calculate the layer thickness and volume from annotated images and present the progression of the measurements. Altris IMS also provides a tool for linear distance measuring of ocular anatomy and ocular lesion distances. The platform supports DICOM format files.

Altris IMS is focused on the center sector of the retina. Altris IMS does not perform optic nerve analysis. Altris IMS has tools for manual area of interest image segmentation and labeling/annotation for healthcare professionals to use and review for their own diagnosis.

The Subject device neither performs any diagnosis, nor provides treatment recommendations. It is solely intended to be used as a support tool by trained healthcare professionals. The software does not use artificial intelligence or machine learning algorithms.

The Subject device is a client-server model. It utilizes a local user/client internet browser-based (frontend) interface used to upload, manage, annotate, and review imaging data. Data is stored and processed on a remote web-based server (backend).

INDICATIONS FOR USE

The Altris IMS is a standalone, browser-based software application intended for use by healthcare professionals to import, store, manage, display, analyze and measure data from ophthalmic diagnostic instruments, including patient data, diagnostic data, clinical images and information, reports, and measurement of DICOM-compliant images. The device is also indicated for manual labeling and annotation of retinal OCT scans.

EQUIVALENCE TO MARKETED DEVICE

Overall, the Subject device is highly similar to the Predicate device with respect to Indications for Use and technological principles. The Comparison tables below compare Indications for Use and Technological Characteristics of the Subject device and Predicate device.

Indications for Use Statement (IFUS)

Device	Indications for Use Statement
Subject Device Altris IMS Altris, Inc.	*The Altris IMS is a standalone, browser-based software application intended for use by healthcare professionals to import, store, manage, display, analyze and measure data from ophthalmic diagnostic instruments, including patient data, diagnostic data, clinical images and information, reports, and measurement of DICOM-compliant images. The device is also indicated for manual labeling and annotation of retinal OCT scans.*
Predicate Device RetinAI Discovery RetinAI Medical AG K211715	*The RetinAI Discovery is a standalone, browser-based software application intended for use by healthcare professionals to import, store, manage, display, analyze and measure data from ophthalmic diagnostic instruments, including: patient data, diagnostic data, clinical images and information, reports, and measurement of DICOM-compliant images. The device is also indicated for manual labeling and annotation of retinal OCT scans.*
Reference Device 3D OCT-1 Maestro Topcon Corporation K170164	*The 3D OCT-1 Maestro with new line CCD has the following intended use and indications for use:* *The Topcon 3D OCT-1 Maestro is a non-contact, high resolution tomographic and biomicroscopic imaging device that incorporates a digital camera for photographing, displaying and storing the data of the retina and surrounding parts of the eye to be examined under Mydriatic and non-Mydriatic conditions.* *The 3D OCT-1 Maestro is indicated for in vivo viewing, axial cross sectional, and three-dimensional imaging and measurement of posterior ocular structures, including retina, retinal nerve fiber layer, macula and optic disc as well as imaging of anterior ocular structures.* *It also includes a Reference Database for posterior ocular measurements which provide for the quantitative comparison of retinal nerve fiber layer, optic nerve head, and the macula in the human retina to a database of known normal subjects. The 3D OCT-1 Maestro is indicated for use as a diagnostic device to aid in the diagnosis, documentation and management of ocular health and diseases in the adult population.*

The wording of the Indications for Use Statement (IFUS) of the Subject device is highly similar to that of the Predicate device, differing only in device name. This does not change the intended use of the devices to import, store, manage, display, analyze and measure data from ophthalmic diagnostic instruments.

The wording of the Indications for Use Statement (IFUS) of the Subject device is similar to that of the Reference device. The Reference device includes imaging equipment and additional imaging measurement and comparison

features. This does not change the fundamental intended use of the devices to store, manage, display, analyze and measure data from ophthalmic diagnostic instruments.

Technological Characteristics

Parameter	**Subject Device** Altris IMS Altris, Inc.	**Predicate Device** RetinAI Discovery RetinAI Medical AG K211715	**Reference Device** 3D OCT-1 Maestro Topcon Corporation K170164
Reason for Predicate	n/a	Ophthalmic software to import, store, manage, display, analyze and measure data from ophthalmic diagnostic instruments	Measurement comparison
Device	System, image management, ophthalmic	System, image management, ophthalmic	Tomography, Optical Coherence
Trade Name	Altris IMS	RetinAI Discovery	3D OCT-1 Maestro
Regulation #	21 CFR 892.2050	21 CFR 892.2050	21 CFR 886.1570
Regulation Name	Medical Image Management and Processing System	Medical Image Management and Processing System	Ophthalmoscope
Product Code	NFJ	NFJ	OBO
Classification	Class II	Class II	Class II
User Population	Trained medical professionals	Trained medical professionals	Trained medical professionals
Device Type	Software only	Software only	Imaging system with storage/management software
Operating System	Internet Web Browser-based • Google Chrome: Version v.88 and later • Mozilla Firefox: Version v.89 and later • Opera: Version v.74 and later • Apple Safari: Version v.15 and later	Internet Web Browser-based • Browsers and versions not specified	PC-based with dedicated software • Operating system not specified
Data and Supported Formats	DICOM-compliant files from an ophthalmic device (Scanning Laser Ophthalmoscope, Fundus photographs, Optical Coherence Tomography unit, etc.)	DICOM-compliant files from an ophthalmic device (Scanning Laser Ophthalmoscope, Fundus photographs, Optical Coherence Tomography unit, etc.)	DICOM-compliant files (based on device labeling) and different types of scans and photography protocols
Supported Machines	DICOM-compliant devices	DICOM-compliant devices	DICOM-compliant devices
Image Annotation and Measurement	Yes	Yes	Yes
Sharing	Share images with current layout with another user via shareable link	Share images with current layout with another user via shareable link	Not defined in device labeling
Biocompatible	n/a	n/a	n/a
Sterility	n/a	n/a	n/a
OTC or Rx	Rx	Rx	Rx

The Subject and Predicate devices are highly similar standalone browser-based software devices intended to display, analyze, and annotate previously acquired images of the eye in order to streamline review of such images by healthcare professionals. Neither the Subject or Predicate devices are used to offer capture components or are used directly to acquire images. The Subject device can be used on a variety of web browsers (i.e., Google Chrome, Mozilla Firefox, Opera, Apple Safari). The Predicate device also operates with an internet web browser interface but has not provided specific browser and version information in public facing documents. Internet web browsers are ubiquitous and regularly updated, so use of a specific browser or browser version number does not impact evaluation of device similarities as the browser is simply the interface to the Subject device and numerous options exist for users. Therefore, the Subject and Predicate are highly similar in the use of a web-browser interface. The Subject and Predicate device feature highly similar capabilities of manual measurement and annotation of OCT imaging.

The K170164 Reference device does not share the same regulation or product code as the Subject device as it is a combined imaging and image management device with the imaging device as the primary product code. Both the Subject and Reference devices are operated from a computer, but the Reference device has a dedicated software program rather than a web-browser based interface. Both the Subject and Reference devices support image annotation and measurement from DICOM-compliant imaging systems and both work with a variety of photography formats. Differences between the Subject and K170164 Reference device software formats do not change the intended uses to i*mport, store, manage, display, analyze and measure data from ophthalmic diagnostic instruments.* The Reference device is included in support of comparative

measurement validation of the Subject device. The use of Predicate device as a standalone, web-browser-based program supports the Subject device web-browser-based program configuration.

Software validation and verification and validation were used to demonstrate the Subject device performs as intended similarly to the Predicate device.

PERFORMANCE DATA

Due to the difficulty in evaluating this type of software, no direct performance bench testing of software to an established standard was performed.

The following non-clinical performance tests were performed to assist in establishing similarity with the Predicate device and suitability for intended use:

- Software Verification
- Software Validation
- Comparative Software measurement study with the K170164 Reference device.

CONCLUSION

Overall, the Indications for Use statement for the Subject and Predicate devices is highly similar.

Overall, the Technological Characteristics of the Subject device are highly similar to the Predicate device.

The conclusions drawn from the nonclinical tests demonstrate that the proposed Subject device is as safe, as effective, and performs as well as the legally marketed Predicate device, according to 807.92(b)(3).

Overall, the Altris IMS software is substantially equivalent to the Predicate device.