August 22, 2024

Centervue Spa
Luca Scienza
Quality and Regulatory Manager
Via San Marco 9H
Padova, 35129
Italy

Re: K234076
Trade/Device Name: iCare ALTIUS CW
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: NFJ
Dated: December 21, 2023
Received: December 22, 2023

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K234076

Device Name
iCare ALTIUS CW

Indications for Use *(Describe)*
iCare ALTIUS CW is a Medical Device Software indicated for the review, processing and analysis of ophthalmic medical images, for the review of video, clinical and diagnostic data, measurements and reports, generated by ophthalmic medical devices or documentation system through computerized networks, to support trained healthcare professionals in the diagnosis and monitoring of several eye pathologies.

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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Regulatory information

Device Name:	iCare ALTIUS CW
Type of 510(k) submission:	Traditional
510(k) number:	K234076
Date:	August 21, 2024
Manufacturer:	CenterVue S.p.A. via San Marco 9H 35129 Padova Italy
510(k) Owner:	CenterVue S.p.A. via San Marco 9H 35129 Padova Italy Phone: +39 049 501 8399 Fax: +39 049 501 8398
FDA Registration Number:	3008422902
Owner/Operator Number:	10032778
Applicant and Contact:	Mr. Luca Scienza CenterVue S.p.A. QARA Manager Via San Marco 9h 35129 Padova, ITALY Email: luca.scienza@icare-world.com Phone: +39 049 501 8399 Fax: +39 049 501 8398
Product Code:	NFJ
Regulation Number:	892.2050
Common name:	Medical image management and processing system
Review Panel:	Ophthalmic
Device Class:	Class II
Indications for use:	iCare ALTIUS CW is a Medical Device Software indicated for the review, processing and analysis of ophthalmic medical images, for the review of video, clinical and diagnostic data, measurements and reports, generated by

ophthalmic medical devices or documentation system through computerized networks, to support trained healthcare professionals in the diagnosis and monitoring of several eye pathologies.

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Device description

iCare ALTIUS CW is a cloud-based software application with a web-based interface able to:

- review medical ophthalmic images, including videos,
- digitally process images,
- review diagnostic data, clinical information and reports,

from ophthalmic diagnostic instruments. CW does not perform automated image analysis but provides advanced imaging manipulation tools.

CW allows to review and process diagnostic data and multiple images with different formats (e.g. PDFs, JPEG, …) and provides the following features:

- image manipulation filters such as zooming, panning, changing brightness and contrast and gamma, RGB filtering,
- side-by-side image comparison (detached or synchronized mode) with different layouts,
- advanced imaging tools, such as flicker between different pictures and mosaics of several images,
- review and print reports generated by ophthalmic devices.

CW integrates with PACS software systems, which provide the medical images and reports, to be analysed by the CW. The patient data and medical images exchange between CW and PACS is done through computerized networks using secured network communication.

The web-based interface of CW is designed to be used through a desktop PC or a laptop using keyboard and mouse (further details in the technical requirements section).
The User Interface is available in the languages required by the applicable regulatory requirement of the country where the device is placed on the market.

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Technical Specifications

iCare ALTIUS CW - TECHNICAL SPECIFICATIONS	
User PC	Desktop or laptop
Display resolution	Minimum: 1280 × 800 pixels
PC RAM	Minimum: 8GB (with minimum 4 GB free RAM for the browser)
Browser	MS Edge version 97.0.1072.55 (January 6, 2022) or later Mozilla Firefox version 96.0 (January 11, 2022) or later Safari version 15.2 (December 14 Dec 2021) or later Chrome version 97.0.4692.71 (January 4, 2022) or later
Internet connection	Reliable broadband connection
Accessory:	No accessories
PACS supported:	iCare ALTIUS
Image processing features	Basic: Zoom, Pan, Brightness, Contrast, Gamma, RGB filtering Image comparison (detached or synchronized) Cup-to-Disc ratio annotation Advanced: Flickering between different pictures and/or imaging modalities Mosaic (montage)

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Predicate devices

The predicate device selected is identified as follows:

Device Name:	FORUM
Manufacturer:	Carl Zeiss Meditec AG
510(k) Number:	K213527
Product Code:	NFJ
Classification Name:	Medical image management and processing system
Regulation No:	892.2050

Comparison of technological characteristics with the predicate device(s)

iCare ALTIUS CW is substantially equivalent to the predicate device except for the following aspects:

- absence of purely database features (delegated to a non-medical device software - PACS)
- provision of measurements only in dimensionless units (cup-to-disc ratio)
- provision of mosaic and flickering features
- different system architecture (Client/Server VS Cloud Software with web interface).

Differences in technological characteristics are limited to the architecture of the system. Such differences are believed to have no effect on the safety and effectiveness of the device, as documented in the Risk Management process, in the Usability Engineering and demonstrated in device testing and verifications.

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Performance data

The following performance data were provided in support of the substantial equivalence determination.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions."; Basic Documentation Level information was submitted. The software also complies with the IEC 62304 standard for software life cycle processes.

Conclusions

Based on the information contained within this submission, it is concluded that iCare ALTIUS CW is substantially equivalent to the identified predicate device already in interstate commerce within the USA, and that any differences that do exist have no effect on the safety and effectiveness of the device.