August 8, 2024

Synthesis Health Intelligence Inc
Amy Gilchrist
General Counsel
22420 Dewdney Trunk Road, Suite 300
Maple Ridge, BC V2X 3J5
Canada

Re: K240724
Trade/Device Name: SynthVISION 1.0.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: August 5, 2024
Received: August 5, 2024

Dear Amy Gilchrist:

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,

for

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
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.

Submission Number *(if known)*

K240724

Device Name

SynthVISION 1.0.0

Indications for Use *(Describe)*

SynthVISION is a software application that can be used within a web -browser to process and view DICOM and non-DICOM image data and associated medical information to aid in the day-to-day diagnostic activities of medical imaging professionals and those involved in the care of a patient.

SynthVISION displays both lossy-compressed and lossless images. Lossy compressed images are always clearly labeled with the type and degree of data compression. The user must determine if the degree of lossy compression is acceptable for their purposes. Prior to making any medical decisions, the user must view the images within the user's scope of practice.

SynthVISION allows for 2D, multi-planar reformatted and 3D image display and manipulation of medical images, including rotation, measurement, annotation, zoom, window width/level and a variety of other standard tools that a user might need to aid in their diagnostic work.

Any display devices must adhere to applicable regulatory standards. Mobile use for mammography is only for reference and referrals.

SynthVISION utilizes modern authorization and authentication mechanisms that enforce secure access for permissioned users who view the imaging data. The system extends beyond the hospital/clinic/health care provider and its internal network. With proper authorization, SynthVISION can be accessed by users outside of the provider's internal network.

SynthVISION does not contact the patient.

Limitations:
Worklists, reporting information, image storage, image transmission, users, roles, and permissions are provided via connectivity to other information systems such as EMRs, Radiology Information Systems, Cardiology Information Systems, and Lab Information Systems and are not a part of the viewer.

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.

SynthVISION 1.0.0
510(k) Summary

510(k) #: K240724
Prepared on: 2024-08-08

Contact Details

Applicant Name: Synthesis Health Intelligence Inc
Applicant Address: 22420 Dewdney Trunk Road, Suite 300 Maple Ridge BC V2X 3J5 Canada
Applicant Contact Telephone: 8328525815
Applicant Contact: Ms. Amy Gilchrist
Applicant Contact Email: agilchrist@synthesis.health

Device Name

Device Trade Name: SynthVISION 1.0.0
Common Name: Medical image management and processing system
Classification Name: System, Image Processing, Radiological
Regulation Number: 892.2050
Product Code(s): LLZ

Legally Marketed Predicate Devices

Predicate #: K172490
Predicate Trade Name (Primary Predicate is listed first): eUnity
Product Code: LLZ

Device Description Summary

SynthVISION is a medical imaging viewing software used with off-the-shelf workstation hardware and web browsers for the 2D & 3D diagnostic visualization of DICOM and non-DICOM medical images by intended users such as trained radiologists, technologists and all others involved in the patient's care.

SynthVISION consists of configurable software-only modules that display and process DICOM and non-DICOM images and associated medical information to aid in the day-to-day operations and workflow of imaging healthcare professionals, clinicians and other healthcare practitioners.

SynthVISION has the following primary features and functions -

- Zero-footprint medical image upload, transfer, and display of medical images between facilities
- Easy access to images for all participants in the healthcare process, including radiologists, technologists, physicians, nurses and others who participate in patient care
- Serves as information and data management system for DICOM and non-DICOM medical images

- Industry-standard tools for image manipulation, annotation and measurement
- Metadata information and orientation labels display
- Advanced image manipulation functions like view synchronization across series, MIP and MPR
- Advanced image processing filters
- Encrypted transmission of medical images through secured networks
- Encrypted storage of medical images
- HIPAA-compliant data management, including centralized storage of user activities via audit trails.

Intended Use/Indications for Use

SynthVISION is a software application that can be used within a web -browser to process and view DICOM and non-DICOM image data and associated medical information to aid in the day-to-day diagnostic activities of medical imaging professionals and those involved in the care of a patient.

SynthVISION displays both lossy-compressed and lossless images. Lossy compressed images are always clearly labeled with the type and degree of data compression. The user must determine if the degree of lossy compression is acceptable for their purposes. Prior to making any medical decisions, the user must view the images within the user's scope of practice.

SynthVISION allows for 2D, multi-planar reformatted and 3D image display and manipulation of medical images, including rotation, measurement, annotation, zoom, window width/level and a variety of other standard tools that a user might need to aid in their diagnostic work.

Any display devices must adhere to applicable regulatory standards. Mobile use for mammography is only for reference and referrals.

SynthVISION utilizes modern authorization and authentication mechanisms that enforce secure access for permissioned users who view the imaging data. The system extends beyond the hospital/clinic/health care provider and its internal network. With proper authorization, SynthVISION can be accessed by users outside of the provider's internal network.

SynthVISION does not contact the patient.

Limitations:
Worklists, reporting information, image storage, image transmission, users, roles, and permissions are provided via connectivity to other information systems such as EMRs, Radiology Information Systems, Cardiology Information Systems, and Lab Information Systems and are not a part of the viewer.

Indications for Use Comparison

The Predicate Device (eUnity) and Subject Device (SynthVISION) are both software-based viewers designed to receive, display, and measure image data and indicated for use to aid in diagnosis for trained healthcare professionals.

Both devices shared common technological characteristics. Both are intended as a zero-download, zero-footprint browser-based viewer. By leveraging the industry standard browser-based technology, both devices enable image data display with off-the-shelf hardware as well as mobile usage.

Both devices can display image data in DICOM format from imaging modalities standard in the provision of care and non-DICOM image data captured in widely used JPEG or PNG format.
The indications for use of the Predicate Device and Subject Device are substantially equivalent. The subject device does introduce the use in primary mammography interpretation. This change does not introduce new/modified risks compared to the general risks that were already addressed by the predicate device.

Technological Comparison

The technological characteristics of SynthVISION in comparison to those of the predicate device, eUnity, are provided below:

Design: SynthVISION is designed as a user-friendly interface for displaying medical images and related data. It has customizable layouts, intuitive navigation tools, and provides fast and reliable performance. These are the same design principles of the predicate device.

Material: Both SynthVISION and the predicate device are software applications and do not have physical material characteristics like hardware devices. However, they require hardware components such as computers, monitors, and network infrastructure to operate efficiently.

Chemical Composition: N/A for software-based PACS viewers.

Principle of Operation: The principle of operation for SynthVISION involves receiving and displaying digital medical images and associated information. This includes functionalities such as image viewing, zooming, panning, measurement tools, image comparison, annotations, and report generation. This is at par with the principle of operation for the predicate device that provides the same functionalities needed to deliver the quality care patients demand. Similar modalities used in the provision of care are supported by both viewers.

Energy Source: N/A for software-based PACS viewers, as they run on computers powered by electricity.

Overall, the technological characteristics are the same for SynthVISION, the subject device and eUnity, the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

The following nonclinical performance tests were conducted to demonstrate safety and performance of SynthVISION as well as show substantial equivalence to the predicate device.

1. Software Verification and Validation:

Purpose: Software testing was conducted on the key software components of SynthVISION 1.0.0 to ensure the reliability, accuracy, and security of image processing and display functionalities.

Tests Included: Verification of software requirements, validation of user interfaces, and testing for robustness and security.

2. Usability Testing:

Purpose: Usability testing assessed the ease of use, user interface design, and overall user experience to ensure that healthcare professionals can effectively and safely use SynthVISION 1.0.0.

Tests Included: User interface evaluations and task performance assessments.

3. Performance Testing:

Purpose: Performance testing evaluated the accuracy and effectiveness of the viewer in processing and displaying medical images, ensuring that it meets specified performance criteria and is equivalent to the predicate device.

Tests Included: Image quality assessments, tool tests, display requirements, etc.

4. System Safety and Risk Analysis:

Purpose: System safety and risk analysis were conducted, identifying and mitigating potential hazards associated with SynthVISION and associated OTS softwares.

Tests Included: Internal and external tests conducted to highlight issues. Risk mitigation strategies were implemented that demonstrated the device's commitment to safety and the prevention of adverse events.

5. Clinical tests:

Not Applicable.

Clinical tests were not conducted as our comprehensive analysis and documentation, including nonclinical tests and performance evaluations, have provided substantial evidence demonstrating the equivalence of SynthVISION to the predicate device.

Below are the conclusions that were drawn based on nonclinical tests conducted comparing SynthVISION and the predicate device:

1. Software Verification and Validation:

Conclusion: Rigorous software verification and validation processes were conducted, ensuring SynthVISION functions accurately and reliably when compared to the predicate device. 100% of the tests passed verification. The results demonstrated that the software meets specified requirements, providing a safe and effective platform for medical image processing and display.

2. Usability Testing:

Conclusion: Usability testing indicated that SynthVISION offers an intuitive and user-friendly interface and provides an equivalent experience to the predicate device. Healthcare professionals can efficiently and safely interact with the device, minimizing the risk of user errors and ensuring effective utilization in a clinical setting.

3. Performance Testing:

Conclusion: The intended use, functionality and performance of the subject device SynthVISION 1.0.0 and predicate device are equivalent. The result of the non-clinical performance testing and bench testing is evidence that the SynthVISION device performs in an equivalent manner to the predicate device.