July 10, 2026

Avara Software
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Dr. Suite #510k
Saint Paul, Minnesota 55114

Re: K262120
Trade/Device Name: Avara Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: June 23, 2026
Received: June 23, 2026

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 (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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262120

Please provide the device trade name(s).

Avara Viewer

Please provide your Indications for Use below.

Avara Viewer is a software only Medical Image Management and Processing System intended to display, process, read, report, communicate, distribute, store, and archive medical data which is available as DICOM data, including mammographic images.
It supports the physician in diagnosis.
For primary image diagnosis in Mammography, only uncompressed or non-lossy compressed images must be used.
Typical users of this system are trained professionals, including but not limited to physicians, radiologists, nurses, medical technicians, and assistants.
Note: Web-based image distribution and mobile device display of mammographic images are not intended for diagnostic purposes.
Mobile device display is not intended for diagnostic purposes.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☒ Neonates/Newborns (Birth to < 29 days old) ☒ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) summary

1. Contact Information

Field	Value
Company Name	Avara Software
Address	5015 4th St N, St Petersburg, FL, 33703
Phone	727-735-2881
Company Contact	Richard Bailey, Project Lead
Email	richie@avarasoftware.com
Date Prepared	2026-06-02

2. Device Information

Field	Value
Trade Name	Avara Viewer
Common Name	DICOM Viewer
Device 510(k) Number	K262120
Software Version	1.0.0
Product Code	LLZ
Regulation Number	21 CFR 892.2050
Device Class	Class II
Panel	Radiology
Type of Use	Prescription Use (21 CFR 801 Subpart D)

3. Predicate Device Information

Field	Value
Predicate Device Name	MedDream
Applicant	Softneta UAB
Predicate Device 510(k) Number	K222320
Date Cleared	December 6, 2022
Product Code	LLZ
Regulation Number	21 CFR 892.2050
Device Class	Class II

4. Device Description

The Avara Viewer is a software-only Medical Image Management and Processing System implemented as a zero-footprint, web-based DICOM viewer. The device is delivered as a modular component and operates entirely within a standard web browser on clinical workstations running Windows, macOS, or Linux. No proprietary hardware, dedicated workstation software installation, or local DICOM storage infrastructure is required. All diagnostic image rendering, measurement computation, and annotation processing occur client-side within the browser environment.

The Avara Viewer is deployed through two access models. In the Avara platform model, users authenticate via email-based credentials and the viewer fetches DICOM data directly from Avara-managed cloud object storage via time-limited presigned HTTPS URLs without server-side proxying. In the SDK integration model, third-party integrators embed the viewer into their own clinical workflows; the viewer fetches DICOM data directly from the integrator's own storage infrastructure via presigned URLs, and DICOM data is never stored or proxied by Avara infrastructure. In both models, DICOM pixel data exists only in browser memory during the active session and is never written to disk by the device.

The cleared device is the Avara Viewer and its direct software dependencies, independent of the deployment context in which it is embedded. The device is functionally identical across all deployment configurations.

The Avara Viewer provides diagnostic display of DICOM medical imaging data across the range of modalities produced by standard clinical imaging systems, with modality-specific display including HU calibration for CT, SUVbw computation for PET, and laterality/view-based hanging protocol for mammography. Advanced rendering capabilities include maximum intensity projection, multiplanar reconstruction (axial, coronal, sagittal), 3D volume rendering, and PET/CT fusion. Measurement tools include line, polyline, angle, Cobb angle, vertebra angle, height difference, cardiothoracic ratio, flatfoot arch, goniometry, bidirectional, ellipse ROI, rectangle ROI, and freeform polygon ROI. Annotation tools include text, arrow, freehand draw, and spine labels. The device supports configurable multi-viewport layouts, multi-monitor display, multi-study and multi-patient display, secondary capture DICOM object creation, study and series export, DICOM Structured Report display, and supplementary non-DICOM media display.

4.1 Key Marketing Claims

The Avara Viewer is a zero-footprint web-based diagnostic DICOM viewer requiring no local software installation. The Avara Viewer provides diagnostic-grade image display, measurement, and annotation across the full range of clinical DICOM modalities. The Avara Viewer is accessible from any network-connected clinical workstation via a standard web browser. The Avara Viewer supports SDK-based integration into existing PACS, EHR, and clinical workflow platforms without requiring server-side DICOM proxying infrastructure.

5. Indications for Use

Avara Viewer is a software only Medical Image Management and Processing System intended to display, process, read, report, communicate, distribute, store, and archive medical data which is available as DICOM data, including mammographic images.
It supports the physician in diagnosis.
For primary image diagnosis in Mammography, only uncompressed or non-lossy compressed images must be used.
Typical users of this system are trained professionals, including but not limited to physicians, radiologists, nurses, medical technicians, and assistants.
Note: Web-based image distribution and mobile device display of mammographic images are not intended for diagnostic purposes.
Mobile device display is not intended for diagnostic purposes.

6. Predicate Device Comparison

Feature	Avara Viewer	MedDream (K222320)	Comments

	(K262120)		
Intended Use	Diagnostic display and management of DICOM medical imaging data, including mammographic images, to support the physician in diagnosis.	Diagnostic display and management of DICOM and HL7 data, including mammographic images and biosignals, to support the physician in diagnosis; also serves as a vendor neutral archive.	Same intended diagnostic display purpose. Avara's intended use is a proper subset of MedDream's; Avara does not claim HL7 data, biosignal processing, or VNA functions. Scope narrowings do not raise new questions of safety or effectiveness.
Indications for Use	Software-only MIMPS intended to display, process, read, report, communicate, distribute, store, and archive DICOM medical imaging data, including mammographic images, to support the physician in diagnosis. Primary mammographic diagnosis restricted to lossless or uncompressed images. Mobile and web-based mammographic display not intended for diagnostic purposes.	Software-only MIMPS intended to display, process, read, report, communicate, distribute, store, and archive DICOM and HL7 data, including mammographic images and biosignals. Serves as a vendor neutral archive. Primary mammographic diagnosis restricted to lossless or uncompressed images. Mobile and web-based mammographic display not intended for diagnostic purposes.	Same indications for use. Avara Viewer's indications for use are a proper subset of MedDream's cleared scope. Avara does not claim HL7 data, biosignal processing, or VNA functions – all scope narrowings that do not raise new questions of safety or effectiveness.
Software-only device	Yes	Yes	Same
Web-based zero-footprint viewer	Yes	Yes	Same

DICOM data display	Yes	Yes	Same
Mammographic image display	Yes – lossless or uncompressed only for primary diagnosis	Yes – lossless or uncompressed only for primary diagnosis	Same
CT display with HU calibration	Yes	Yes	Same
PET display with SUVbw	Yes	Yes	Same
Multimodality DICOM display	Yes	Yes	Same
Windowing (window/level)	Yes	Yes	Same
Pan, zoom, rotate	Yes	Yes	Same
Cine playback	Yes	Yes	Same
Maximum intensity projection (MIP)	Yes	Yes	Same
Multiplanar reconstruction (MPR)	Yes – axial, coronal, sagittal	Yes – axial, coronal, sagittal	Same
3D volume rendering	Yes	Yes	Same
PET/CT fusion	Yes	Yes	Same
Cross-reference lines	Yes	Yes	Same
Crosshair synchronization	Yes	Yes	Same
Synchronized scrolling	Yes	Yes	Same
Multi-viewport layout	Yes	Yes	Same

Multi-monitor support	Yes	Yes	Same
Mammography hanging protocol	Yes	Yes	Same
Line measurement	Yes	Yes	Same
Angle measurement	Yes	Yes	Same
Cobb angle	Yes	Yes	Same
Vertebra angle	Yes	Yes	Same
Height difference	Yes	Yes	Same
Cardiothoracic ratio	Yes	Yes	Same
Flatfoot arch measurement	Yes	Yes	Same
Goniometry	Yes	Yes	Same
ROI (ellipse, rectangle, freeform)	Yes	Yes	Same
Calibration tool	Yes	Yes	Same
Text, arrow, freehand annotation	Yes	Yes	Same
Spine labeling	Yes	Yes	Same
Annotation persistence	Yes	Yes	Same
Key object support	Yes	Yes	Same
Secondary capture	Yes	Yes	Same
Study/series download	Yes	Yes	Same
Structured report	Yes	Yes	Same

display			
Non-DICOM media display	Yes	Yes	Same
Mobile device diagnostic use	No	No	Same – both contraindicated
Magnifying glass	No	Yes	Not present in Avara Viewer. Functionally superseded by configurable mouse wheel zoom and double-click zoom, which provides equal or greater magnification capability. Does not raise new questions of safety or effectiveness.
Ruler	No	Yes	Named variant of the line tool with identical geometry. Avara's line tool implements the identical measurement operation. Does not raise new questions of safety or effectiveness.
Segmentation and volume tools	No	Yes	Requires validated ML or heuristic algorithms not within this submission scope. Absence reduces risk of clinically misleading outputs. Does not raise new questions of safety or effectiveness.

Myocardium ROI	No	Yes	Requires validated boundary delineation algorithms. Standard ROI tools cover clinical need. Does not raise new questions of safety or effectiveness.
Propagate ROI / Paste ROI	No	Yes	Requires validated inter-slice geometric correspondence tracking. Manual ROI placement is standard of care. Does not raise new questions of safety or effectiveness.
TT-TG distance	No	Yes	Subspecialty orthopedic surgical planning tool outside general diagnostic scope. Derivable from line and angle primitives. Does not raise new questions of safety or effectiveness.
HTO angles	No	Yes	Osteotomy surgical planning tool. Derivable from angle primitive. Does not raise new questions of safety or effectiveness.
Time intensity curve	No	Yes	Workflow convenience feature. Information accessible via frame navigation and intensity-on-hover. Does not raise new questions of safety

			or effectiveness.
Swap viewports	No	Yes	Covered by drag-and-drop series reassignment. Does not raise new questions of safety or effectiveness.
Asymmetric viewport splitting	No	Yes	All clinically relevant layouts covered by uniform viewport configurations. Does not raise new questions of safety or effectiveness.
Flexpoly	No	Yes	Equivalent to freeform polygon ROI with additional pixel statistics. Does not raise new questions of safety or effectiveness.
CAD marks as vendor-specific objects	No	Yes	Standard DICOM overlay and secondary capture CAD marks are supported in the Avara Viewer. Proprietary vendor-specific CAD objects are not rendered, as supporting them would require per-vendor validation outside the scope of this submission. Does not raise new questions of safety or effectiveness.
Curved MPR	No	Yes	Not implemented in cleared device.

			Standard planar MPR fully supported and validated. Does not raise new questions of safety or effectiveness.
Digital subtraction angiography	No	Yes	DSA not implemented. XA/RF series supported for standard diagnostic display. Does not raise new questions of safety or effectiveness.
HL7 data	No	Yes	Scope narrowing – Avara is DICOM-only. HL7 is a messaging standard, not an imaging data type. Does not raise new questions of safety or effectiveness.
Biosignal processing	No	Yes	Scope narrowing. Biosignal data as DICOM secondary capture displayable. Does not raise new questions of safety or effectiveness.
Vendor neutral archive	No	Yes	Scope narrowing – VNA is a platform or infrastructure function, not a viewer function. Does not raise new questions of safety or effectiveness.
Bidirectional measurement tool	Yes	No	Compositional derivative of validated line

			primitive. Two perpendicular line distances using identical calibration pipeline. Does not raise new questions of safety or effectiveness.
Spine labeling series propagation	Yes	No	Workflow efficiency feature. Labels identical to manually placed labels. No new clinical output. Does not raise new questions of safety or effectiveness.
Cross-reference type selection	Yes	No	UX control over cross-reference display mode. Underlying geometry identical. Does not raise new questions of safety or effectiveness.
Deployment architecture	Client-side direct-fetch; DICOM data never stored or proxied by Avara Viewer; SDK webhook-driven integration	Server-side Docker containerization with DICOM proxying	Different but more protective architecture. Reduces PHI surface area, simplifies attack surface, improves scalability. Clinical function identical. Does not raise new questions of safety or effectiveness.

6.1 Summary of Technological Characteristics and Comparison

The Avara Viewer and MedDream share the same indications for use as software-only Medical Image Management and Processing Systems for diagnostic display of DICOM medical imaging data. Both devices provide the complete set of clinically significant diagnostic display,

measurement, annotation, rendering, and workflow capabilities required for general diagnostic radiology practice. The Avara Viewer's indications for use are a proper subset of MedDream's cleared scope with no expansion in any clinically significant dimension.

Differences in technological characteristics between the two devices fall into three categories. Features present in MedDream but absent in the Avara Viewer are either redundant with equivalent or superior tools present in both devices, limited to subspecialty surgical planning workflows outside the general diagnostic scope, dependent on unvalidated algorithms whose omission reduces rather than increases clinical risk, or workflow convenience. Features present in the Avara Viewer but absent in MedDream are compositional derivatives of validated measurement primitives or UX enhancements that introduce no new clinical output. The deployment architecture difference represents a more protective implementation that reduces PHI surface area and system complexity relative to the predicate. None of the identified differences raise new questions of safety or effectiveness relative to the predicate device.

7. Discussion of Non-Clinical Testing

7.1 Software Validation and Verification

Software verification and validation was conducted on the Avara Viewer in accordance with FDA guidance "Content of Premarket Submissions for Device Software Functions" (2023). The Avara Viewer is classified as Major Concern software. The software V&V program encompassed unit testing, integration testing, and browser-level end-to-end testing across all supported browser engines. All software requirements were verified and the indications for use were successfully validated.

7.2 Measurement Accuracy

Measurement accuracy testing was conducted as a comparative evaluation of the Avara Viewer against the MedDream Viewer (K222320) as a calibrated reference standard across all measurement-based annotation tools. Testing was performed at identical anatomical landmarks in both viewers simultaneously across all measurement tool types. All measurement outputs met the pre-specified acceptance criteria and no statistically significant difference was detected between the two devices. DICOM conformance testing was additionally conducted across a representative set of studies spanning multiple modalities, manufacturers, and encoding types, with all studies passing all verification criteria.

8. Discussion of Clinical Validation

A prospective multi-reader multi-case non-inferiority reader study was conducted to demonstrate that the Avara Viewer enables diagnostic radiologists to detect clinically significant findings at a level non-inferior to the MedDream predicate device. The study enrolled independent board-certified diagnostic radiologists who evaluated deidentified CT and MR studies sourced from multiple manufacturers across multiple anatomical regions. A balanced crossover design with washout period was employed. Ground truth was established by majority consensus of independent board-certified ground truth readers.

The primary non-inferiority hypothesis was met. The lower bound of the one-sided 97.5% confidence interval for the mean paired sensitivity difference exceeded the pre-specified non-inferiority margin, and the null hypothesis was rejected at the one-sided $\alpha = 0.025$ significance level. Exploratory subgroup analyses confirmed consistency of the finding across modality, manufacturer, and anatomical region. A pre-specified sensitivity analysis confirmed robustness to individual reader influence. Secondary endpoint and false positive rate analyses provided additional corroborating evidence of equivalence between the two devices.

9. Conclusion

The Avara Viewer (K262120) shares the same indications for use as the MedDream predicate device (K222320) as a software-only Medical Image Management and Processing System for diagnostic display of DICOM medical imaging data, including mammographic images, to support the physician in diagnosis. Both devices share the same product code (LLZ), regulation (21 CFR 892.2050), and device class (II).

The Avara Viewer has different technological characteristics from MedDream. These differences have been systematically analyzed and none raise new questions of safety or effectiveness. Features absent from the Avara Viewer relative to MedDream are redundant with equivalent tools, outside the general diagnostic scope, dependent on unvalidated algorithms whose omission reduces clinical risk, or workflow convenience and proprietary vendor-specific features with no independent diagnostic function. Features present in the Avara Viewer but absent in MedDream are compositional derivatives of validated measurement primitives or UX enhancements with no new clinical output. The deployment architecture difference represents a more protective implementation that reduces PHI surface area and system complexity relative to the predicate.

Non-clinical performance testing demonstrates that the Avara Viewer performs equivalently to the predicate device across software verification and validation, DICOM conformance, and measurement accuracy. Clinical validation through a prospective multi-reader multi-case

non-inferiority reader study demonstrates that the Avara Viewer enables diagnostic radiologists to detect clinically significant findings at a level non-inferior to the predicate device, with consistency confirmed across modality, manufacturer, and anatomical region.

Based on the device comparison and the performance testing results, the Avara Viewer (K262120) is substantially equivalent to the MedDream Viewer (K222320) for the indications for use stated in the subject device labeling.