AS Software, LLC
Becky Piroga
FDA Compliance Manager
560 Sylvan Ave.
Englewood Cliffs, NJ 07632

February 19, 2026

Re: K260205
Trade/Device Name: AS Software Version Asera
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: January 23, 2026
Received: January 23, 2026

Dear Becky Piroga:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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, PhD
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

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.	K260205

Please provide the device trade name(s).

AS Software Version Asera

Please provide your Indications for Use below.

AS Software Version Asera is intended to automate the management of patient information. The system allows image acquisition, review, documentation, storage, archiving, and reporting.

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)

Special 510(k) Summary
AS Software Version Asera
In accordance with 21 CFR 807.92

I. SUBMITTER

Manufacturer:	AS Software, LLC
Address:	560 Sylvan Ave Englewood Cliffs, NJ USA 07632
Phone:	201-541-1900
FDA Registration:	3005207094
Contact Person:	Becky Piroga, FDA Compliance Manager
Date Prepared:	January 23, 2026

II. SUBJECT (MODIFIED) DEVICE

Device Proprietary Name:	AS Software Version Asera
Common Name:	Medical Image Management and Processing System
Manufacturer:	AS Software, LLC
Classification Name:	System, Image Processing, Radiological
Primary Product Code:	LLZ
Regulation Number:	21 CFR 892.2050
Device Classification:	Class II

III. PREDICATE (UNMODIFIED) DEVICE

Device Proprietary Name:	AS-OBGYN Information System
510k Number:	K051639
Common Name:	Medical Image Management and Processing System
Manufacturer:	AS Software, LLC
Classification Name:	System, Image Processing, Radiological
Primary Product Code:	LLZ
Regulation Number:	21 CFR 892.2050
Device Classification:	Class II

IV. DEVICE DESCRIPTION

AS Software Version Asera is an interactive web application which allows for the management of patient information and images. The ultrasound reporting and management system provides the capability to capture examination data and images from ultrasound machines and to generate electronic and printed medical reports from them.

AS Software Version Asera interfaces with HL7 standards and DICOM modality machines.

AS Software Version Asera is a software-only device. All hardware used by AS Software Version Asera (including computers, storage drives, network interface, monitors, printers, and ultrasound peripherals) is commercial off-the-shelf equipment and does not require an additional dedicated energy source.

AS Software Version Asera is an updated version of the current AS Software. It provides a modernized user interface and allows for multitenancy.

V. INDICATIONS FOR USE

AS Software Version Asera is intended to automate the management of patient information. The system allows image acquisition, review, documentation, storage, archiving, and reporting.

VI. INTENDED USERS / USE ENVIRONMENT

AS Software Version Asera is intended for use by sonographers, obstetricians, gynecologists, perinatologists, radiologists, and cardiologists. It is designed for use in hospitals, medical offices, and similar healthcare environments.

VII. COMPARISON TO THE PREDICATE DEVICE

Feature	**Subject (Modified) Device:** AS Software Version Asera	**Predicate (Unmodified) Device:** AS-OBGYN Information System	**Comparison**
Manufacturer	AS Software, LLC	AS Software, LLC	Same
Intended Use	Intended to automate the management of patient information. The system allows image acquisition, review, documentation, storage, archiving, and reporting.	Intended to automate the management of patient information. The system allows image acquisition, review, document, storage, archive, and reporting.	Same (edited for grammar)
Intended Users	Sonographers, obstetricians, gynecologists, perinatologists, radiologists, cardiologists.	Obstetricians, gynecologists, perinatologists, radiologists, cardiologists.	Same (clarified ‘sonographers’ as its own role)
Use Environment	Hospitals, medical offices	Hospitals, medical offices	Same
Device Type	Medical image management and processing system	Medical image management and processing system	Same
Device Regulation	21 CFR 892.2050	21 CFR 892.2050	Same
Device Classification	Class II	Class II	Same

Product Code	LLZ	LLZ	Same
Hardware	Commercial Off-The-Shelf (does not require dedicated energy source)	Commercial Off-The-Shelf (does not require dedicated energy source)	Same
Image Input and Interfaces	DICOM HL7	DICOM HL7	Same
Image Modality	Ultrasound	Ultrasound	Same
Data Privacy and Security	Falls under the umbrella of the manufacturer's SOC 2 and HIPAA compliance	Falls under the umbrella of the manufacturer's SOC 2 and HIPAA compliance	Same
Architecture	Serverless, cloud hosting with AWS, modern frontend framework allows for multitenancy	Cloud hosting with Azure or on-prem	Similar
Patient Contact	None (software only)	None (software only)	Same
Software Documentation Level	Basic	Basic	Same

VIII. TECHNOLOGICAL CHARACTERISTICS

Comparisons to its predicate, an earlier version of the AS Software system, show the technological characteristics to be substantially equivalent. The proposed changes are functionally identical to the predicate device.

IX. SOFTWARE TESTING AND PERFORMANCE DATA

A summary of software verification and validation studies are provided in support of a substantial equivalence determination for the changes made to the subject device.

X. CYBERSECURITY TESTING

Cybersecurity testing for AS Software Version Asera was conducted and documented in accordance with the FDA Guidance Document "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" from June 2025.

XI. SUMMARY OF CLINICAL DATA

Clinical studies are not necessary to validate the safety and effectiveness of the software in AS Software Version Asera.

XII. CONCLUSION

Results of testing have demonstrated that AS Software Version Asera meets requirements for its intended use. The information provided above supports that AS Software Version Asera is substantially equivalent to the predicate device: the intended use and indications for use are the same, the majority of the features are the same, and no new concerns regarding safety or effectiveness were raised during testing.