Aspen Imaging Healthcare Inc
% Dave Kim
Regulatory Affairs Consultant
Mtech Group LLC
7505 Fannin St. Suite 610
Houston, Texas 77054

February 12, 2025

Re: K241425
Trade/Device Name: AspenView
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: January 6, 2025
Received: January 6, 2025

Dear Dave Kim:

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, 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

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.

510(k) Number *(if known)*
K241425

Device Name

AspenView

Indications for Use *(Describe)*

AspenView is indicated for use in general radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures (excluding fluoroscopic, angiographic, and mammographic applications). The main features of this software are storing acquired images, data management, image processing and image stitching.

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.

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ASPEN IMAGING
HEALTHCARE

1. Traditional 510(k) SUMMARY: K241425

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR Part 807.92.

Date 510K summary prepared : February 7, 2025

Submitter's Name, address, telephone number, a contact person:

Submitter's Name :	Aspen Imaging Healthcare Inc
Submitter's Address:	801 Jupiter Rd Suite 200, Plano, TX 75074, USA
Contact Person:	Mr. Casey Lee, Vice President (casey.lee@aspenimaging.com)
Submitter's Telephone:	(+1) 214-257-0113
Contact person:	
Official Correspondent:	Dave Kim, MBA (davekim@mtechgroupllc.com)
	Mtech Group LLC
Address:	7505 Fannin St. Ste 610, Houston, TX 77054
Telephone:	(+1) 713-467-2607

Name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name, if known:

Trade/proprietary name:	AspenView
Regulation Name:	Medical Image Management And Processing System
Regulation Number:	21 CFR 892.2050
Regulatory Class:	II
Product Code:	LLZ

Predicate Device	
Manufacturer:	DRTECH Corporation
Device:	EConsole1
510(k) Number:	K231225
Classification Name:	Medical Image Management And Processing System
Regulatory Number:	21 CFR 892. 2050
Regulatory Class:	II
Product Code:	LLZ

2. Device Description

AspenView software is designed for use by radiologists and radiology technicians for annotation in the X-ray images. The AspenView software is developed to use Aspen Imaging Flat Panel DR Detector and Aspen Imaging Healthcare Inc Image Viewer. The purpose of AspenView software is for the doctor to annotate X-ray images and then to print out with patient information or sent to another PACS system.

A client user needs to install AspenView first in the recommended PC environment. After installation, the client user chooses a DICOM format in the uploaded patient list to be annotated, and then annotation is written by user after reviewing of image chosen. After annotation has completed it can be printed out, saved or sent to another PACS system.

AspenView software includes an image stitching function to read multiple medical images at one time by stitching them to one image based on overlapping areas. It supports DICOM 3.0 which is standard of medical image format as well as Tiff and Raw images. It provides additional functions such as image retrieval, storage, and transmission.

3. Indications for Use

AspenView is indicated for use in general radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures (excluding fluoroscopic, angiographic, and mammographic applications). The main features of this software are storing acquired images, data management, image processing and image stitching.

4. Summary of Design Control Risk management

After the analysis of risk management, there are no more risk factors and no more actions needed either. Risk management, during the life cycle from product planning, design process to follow- up management, identified foreseeable risks in accordance with ISO 14971:2019 (Recog. No: 5-125), IEC 62304:2015 (Recog. No: 13-79) and ISO 13485:2019/AC2016 standards.
The validation of risk management was performed by the radiologist who had the experience in clinical field according to the risk management plan.

5. Comparison with predicate device:

AspenView is a medical software that digitizes signals received from the detector and displays x-ray images. Additionally, it allows for the entry of patient information, image capture details, and other necessary references for enhanced convenience. The technological characteristics of AspenView are substantially equivalent to those of Econsole1, the predicate device.
Functionally, it mirrors the capabilities of the predicate device. AspenView does not have control over exposure settings, electrical adjustments, or the calibration of the X-ray system. Furthermore, AspenView is validated to interface with the Aspen Imaging detector, IODR1417 (K241346).

6. Substantial Equivalence

Characteristic	Proposed : AspenView	Predicate Device: EConsole1	Remark
Manufacturer	Aspen Imaging Healthcare Inc	DRTECH Corporation	

510(k) number	K241425	K231225	
Intended Use	AspenView is indicated for use in general radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures (excluding fluoroscopic, angiographic, and mammographic applications). The main features of this software are storing acquired images, data management, image processing and image stitching.	EConsole1 is indicated for use in general radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures (excluding fluoroscopic, angiographic, and mammographic applications). The main features of this software are controlling and interfacing the detector, controlling the x-ray generator acquisition settings, storing acquired images, data management and image processing	Same
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	Same
Operating System Requirement	Windows 10 and Windows based operating system	Windows 7 or Windows 8 or Windows 10	Similarity
Acquisition devices	Digital X-ray Detector	Digital X-ray Detector	Same
Software Function	Image viewing Image search Image storage Image annotation Image measurement Image processing Image stitch	Image viewing Image search Image storage Image annotation Image measurement Image processing Image stitch Generator Control	Same
DICOM Compliance	Yes	Yes	Same

There are no significant differences between AspenView and the predicate device that would adversely affect the use of the product. It is substantially equivalent to these devices in design, function and operational principles and intended use.

7. Non-Clinical Performance Data

Safety testing and documentation was performed in accordance with IEEE 1012-2012, Standard for System and Software Verification and Validation. [AspenView-SVsR]

Software information is provided in accordance with FDA guidance: "The content of premarket submissions for software contained in medical devices."

Cybersecurity information is provided in accordance with FDA guidance: "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

8. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Aspen Imaging Healthcare Inc concludes that AspenView is substantially equivalent to predicate device as described herein.