January 16, 2026

Softlink International Private Limited
% Sakthileela Nagaiyan
Team Lead (USFDA Compliance - Medical Device)
I3CGLOBAL Reghelps PVT Ltd
MR-02, D-4, First Floor, ClayWorks Shankaraa
H&G, Shankaraa, Kanakapura Rd, Doddakallasandra
Bengaluru, Karnataka 560062
India

Re: K252634
Trade/Device Name: Imagine® Enterprise Suite
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: December 11, 2025
Received: December 11, 2025

Dear Sakthileela Nagaiyan:

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,

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

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.	K252634

Please provide the device trade name(s).

Imagine® Enterprise Suite

Please provide your Indications for Use below.

Imagine® Enterprise Suite (IES) is a medical diagnostic device that receives, stores, and shares the medical images from and to DICOM-compliant entities such as imaging modalities (such as X-ray Angiograms (XA), Echocardiograms (US), MRI, CT, CR, DR, IVUS, OCT, PET and SPECT), external PACS, and other diagnostic workstations. It is used in the display and quantification of medical images, after image acquisition from modalities, for post-procedure clinical decision support. It constitutes a PACS for the communication and storage of medical images and provides a worklist of stored medical images that can be used to open patient studies in one of its image viewers. It is intended to display images and related information that are interpreted by trained professionals to render findings and/or diagnosis, but it does not directly generate any diagnosis or potential findings. Not intended for primary diagnosis of mammographic images. Not intended for intra-procedural or real-time use. Not intended for diagnostic use on mobile devices.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

SoftLink International	**SOFTLINK INTERNATIONAL PRIVATE LIMITED** 2, Anand Park, Aundh, Pune - 411 007, India.
510(k) SUMMARY	

510(k) SUMMARY (510(k) number**)**

[AS REQUIRED BY 21CFR807.92]

K252634

I. SUBMITTER

510(k) Owner's Name	:	SOFTLINK INTERNATIONAL PRIVATE LIMITED
Address	:	2 Anand Park, Aundh, Pune 411007, INDIA
Telephone	:	+91-20-66044444
Fax Number	:	+91-20-25883784
Contact person	:	Prakash S. Kamat
Designation	:	Managing Director
Contact Number	:	+91-98230821280
Contact Email	:	prakash@softlinkinternational.com
Date of Summary Prepared	:	01.08.2025

II. DEVICE

Trade Name	:	Imagine® Enterprise Suite
Device Common Name	:	Medical image management and processing system
Device Classification Name	:	Automated radiological image processing software
Class	:	Class II
Regulation Number	:	21 CFR 892.2050
Product Code	:	QIH, LLZ

III. PREDICATE DEVICES

Primary Predicate Device

Predicate Device Name	:	MPXA-2000
510(k) Number	:	K222036
Device Classification Name	:	Automated Radiological Image Processing Software
Class	:	Class II
Regulation Name	:	Medical image management and processing system
Regulation Number	:	21 CFR 892.2050
Product Code	:	QIH

Reference Predicate Device

Predicate Device Name	:	Syngo.via View&GO (Version VA40A)
510(k) Number	:	K230196
Device Classification Name	:	System, image processing, radiological
Class	:	Class II
Regulation Name	:	Medical image management and processing system
Regulation Number	:	21 CFR 892.2050
Product Code	:	LLZ

IV. DEVICE DESCRIPTION

The Imagine® Enterprise Suite (IES) has, as its backbone, the IES PACS – a DICOM stack for the communication and storage of medical images. It is based on its predecessor, the HCP DICOM Net® PACS (K023467). The IES is made up of the following modules:

IES_EntViewer: This viewer module can be launched from the IES PACS Worklist and is intended primarily for the review and manipulation of angiographic X-ray images. It also supports the review of images from other modalities in single or combination views, thereby serving as a general-purpose multi-modality viewer.

IES_EchoViewer: This viewer module can be launched from the IES Worklist and is intended for specialized viewing, manipulation, and measurements of Echocardiography images.

IES_RadViewer: This viewer module can be launched from the IES Worklist and is intended for specialized viewing, manipulation, and measurements of Radiological images. It also supports the fusion of Radiological images (such as MRI and CT) with Nuclear Medicine images (such as PET and SPECT).

IES_ZFPViewer: This viewer is intended for non-diagnostic review of medical images over a web browser. It supports an independent worklist and a viewing component that requires no installation for the end user. It works within an intranet or over the internet via user-provided VPN or static IP.

AngioQuant: This module can be launched from the IES_EntViewer to perform automatic quantification of coronary arteries. It uses, as input, the cardiac angiogram studies stored on the IES PACS. It is intended for display and quantification of Xray angiographic images after image acquisition in the cathlab, for post-procedure clinical decision support within the cathlab workflow. It is not intended for intra-procedural or real-time use. The Imagine® Enterprise Suite (IES) is integrated with ML only for the segmentation of coronary vessels from X-ray angiographic images and uses deep learning methodology for image analysis.

V. INDICATIONS FOR USE

Imagine® Enterprise Suite (IES) is a medical diagnostic device that receives, stores, and shares the medical images from and to DICOM-compliant entities such as imaging modalities (such as X-ray Angiograms (XA), Echocardiograms (US), MRI, CT, CR, DR, IVUS, OCT, PET and SPECT), external PACS, and other diagnostic workstations. It is used in the display and quantification of medical images, after image acquisition from modalities, for post-procedure clinical decision support. It constitutes a PACS for the communication and storage of medical images and provides a worklist of stored medical images that can be used to open patient studies in one of its image viewers. It is intended to display images and related information that are interpreted by trained professionals to render findings and/or diagnosis, but it does not directly generate any diagnosis or potential findings. Not intended for primary diagnosis of mammographic images. Not intended for intra-procedural or real-time use. Not intended for diagnostic use on mobile devices.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

Comparison Table 1: This table presents a comparison between the proposed device, Imagine® Enterprise Suite (IES), and the primary predicate device, MPXA-2000. This comparison highlights the similarities in concern to Automatic Quantification of XA Angiogram images and differences between the AngioQuant module of the Imagine® Enterprise Suite and the MPXA-2000.

Sl. No	Features compared	Proposed Device	Primary Predicate Device	Result
1.	510(k) Number	-	K222036	NA
2.	Manufacturer	Softlink International Pvt Ltd	Medipixel, Inc.	NA
3.	Classification	Class II	Class II	Same
4.	Product Code	QIH, LLZ	QIH	Same LLZ product code is covered in the other modules. i.e. IES_ENTVIEWER, IES_ECHOVIEWER, IES_RADVEIWER, IES_ZFPVIEWER.
5.	Intended use	Imagine® Enterprise Suite (IES) is a medical diagnostic device that receives, stores, and shares the medical images from and to DICOM-compliant entities such as imaging modalities (such as X-ray Angiograms (XA), Echocardiograms (US), MRI, CT, CR, DR, IVUS, OCT, PET and SPECT), external PACS, and other diagnostic workstations. It is used in the display and quantification of medical images, after image acquisition from modalities, for post-procedure clinical decision support. It constitutes a PACS for the communication and storage of medical images and provides a worklist of stored medical images that can be used to open patient studies in one of its image viewers. It	MPXA-2000 is software intended to be used for performing calculations in X-ray angiographic images of the coronary arteries. These calculations are based on vessel contours which are automatically detected by the software and subsequently presented for review and manual editing. The analysis results obtained with MPXA-2000 are intended for use by cardiologists and radiologists: - to support clinical decisions concerning the coronary arteries. - to support the evaluation of intervention or drug therapy applied for conditions of the coronary arteries.	Same The intended use of IES remains consistent for both the interpretation and quantification of images.

Sl. No	Features compared	Proposed Device	Primary Predicate Device	Result
		is intended to display images and related information that are interpreted by trained professionals to render findings and/or diagnosis, but it does not directly generate any diagnosis or potential findings. Not intended for primary diagnosis of mammographic images. Not intended for intra-procedural or real-time use. Not intended for diagnostic use on mobile devices.		
6.	Indication For Use	Imagine® Enterprise Suite is a software package that aids the visualization and quantification of various medical images in DICOM format, when the patient is NOT in life-threatening state of health, and the time for medical decision is NOT critical. Typical users of this system are trained professionals, including but not limited to physicians, radiologists, cardiologists, nurses, medical technicians, and assistants.	MPXA-2000 is indicated for use in clinical settings where validated and reproducible quantified results are needed to support the calculations in X-ray angiographic images of the coronary arteries, for use on individual patients with coronary artery disease (CAD). MPXA 2000 is indicated for use in adult patients only. When the quantified results provided by MPXA-2000 are used in a clinical setting on X ray images of an individual patient, they can be used to support the clinical decision-making for the diagnosis of the patient or the evaluation of the treatment applied. In this case, the results are explicitly not to be regarded as the sole, irrefutable basis for clinical diagnosis, and they are only intended	Same

Sl. No	Features compared		Proposed Device	Primary Predicate Device	Result
				for use by the responsible clinicians.	
7.	Prescription Use or OTC Use		Prescription use	Prescription use	Same
8.	DICOM-compliant		Yes	Yes	Same
9.	List of Modality support		X-ray Angiograms (XA)	X-ray	Same
10.	Web Diagnostic Viewer		Standalone Software	Standalone software	Same
11.	Input Data type		X-Ray angiography in DICOM format	X-Ray angiography in DICOM format (vendor independent)	Same
12.	Manual editing of automatic results by user		Yes	Yes	Same
13.	Calibration		Automatic calibration based on calibration factor in DICOM file OR automatic segmentation of catheter from image.	Automatic calibration based on isocenter calibration factor in DICOM file Other manual calibration options (catheter calibration)	Same
14.	Automatic angiographic series loading into the software from the angiography equipment		The angiographic equipment or modality first exports the angiographic series to the IES PACS in DICOM format. Angiographic series are loaded into the software from the IES PACS.	Yes	Same
15.	Visualization/ Edit Tools		Zooming, Panning, Editing Vessel Contours.	Zooming, Panning, Editing Vessel Contours, Angle, Length, Area, Text Annotation	Same
16.	Quantitative Analysis	Automated 2D arterial contour segmentation	Yes	Yes	Same
		Classification of vessel types	Manually by user	Yes LAD, LCX, and RCA	Same
		Optional Stent analysis including stent edges	No	No	Same

Sl. No	Features compared		Proposed Device	Primary Predicate Device	Result
17.	Analysis Results	Results for multiple lesions and additional user-defined ROI[a)]	Results for multiple lesions. No user-defined ROIs are supported.	Results for multiple lesions and additional user-defined ROI[a)]	Same
		Vessel analysis	Main and side branch	main and side branch	Same
		Vessel quantifications	% Diameter Stenosis, Minimum Lumen Diameter (MLD), Proximal and Distal Diameters (at P- and D marker positions), Stenosis Length, Reference Diameter	% Diameter Stenosis, Minimum Lumen Diameter (MLD), Proximal and Distal Diameters (at P- and D marker positions), ROI[a)] Length, Reference Diameter	Same
		Stent-related statistics	No	No	Same
18.	Ventricle analysis		No	No	Same
19.	Automatically load and visualize ECG data acquired from the DICOM file		No	Yes	Different
20.	Automatic EoD (End of Diastole) phase detection in DICOM file based on ECG.		No	Yes	Different
21.	Data Reporting		Patient and Study Details, Calibration, Annotation, Measurement, and Analysis Details.	Patient and Study Details, Calibration, Annotation, Measurement, and Analysis details.	Same
22.	Export file formats		PDF	PDF, Excel	Same

Comparison Table 2: This table presents a comparison between the proposed device, Imagine® Enterprise Suite (IES), and the reference predicate device, Syngo.via View&GO VA40A. This comparison highlights the similarities and differences among the IES_ENTViewer, IES_EchoViewer, IES_RadViewer, and IES_ZFPViewer modules of the Imagine® Enterprise Suite (IES) and the Syngo.via View&GO system.

Sl. No	Features compared	Proposed Device	Reference Predicate Device	Result
1.	510(k) Number	-	K230196	NA
2.	Manufacturer	Softlink International Pvt Ltd	Siemens Healthcare GmbH	NA

Sl. No	Features compared	Proposed Device	Reference Predicate Device	Result
3.	Classification	Class II	Class II	Same
4.	Product Code	QIH, LLZ	LLZ	Same QIH product code is covered in the AngioQuant Module
5.	Intended use	Imagine® Enterprise Suite (IES) is a medical diagnostic device that receives, stores, and shares the medical images from and to DICOM-compliant entities such as imaging modalities (such as X-ray Angiograms (XA), Echocardiograms (US), MRI, CT, CR, DR, IVUS, OCT, PET and SPECT), external PACS, and other diagnostic workstations. It is used in the display and quantification of medical images, after image acquisition from modalities, for post-procedure clinical decision support. It constitutes a PACS for the communication and storage of medical images and provides a worklist of stored medical images that can be used to open patient studies in one of its image viewers. It is intended to display images and related information that are interpreted by trained professionals to render findings and/or diagnosis, but it does not directly generate any diagnosis or potential findings. Not intended for primary diagnosis of mammographic images. Not intended for intra-procedural or real-time use. Not intended for diagnostic use on mobile devices.	Syngo.via View&GO is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images. It can be used as a stand-alone device or together with a variety of cleared and unmodified syngo-based software options. syngo.via View&GO supports interpretation and evaluation of examinations within healthcare institutions, for example, in Radiology, Nuclear Medicine and Cardiology environments. The system is not intended for the displaying of digital mammography images for diagnosis in the U.S.	Same

Sl. No	Features compared	Proposed Device	Reference Predicate Device	Result
6.	Indication For Use	Imagine® Enterprise Suite is a software package that aids the visualization and quantification of various medical images in DICOM format, when the patient is NOT in life-threatening state of health, and the time for medical decision is NOT critical. Typical users of this system are trained professionals, including but not limited to physicians, radiologists, cardiologists, nurses, medical technicians, and assistants.	Syngo.via View&GO is indicated for image rendering and post-processing of DICOM images to support the interpretation in the fields of radiology, nuclear medicine, and cardiology.	Same
7.	Prescription Use or OTC Use	Prescription use	Prescription use	Same
8.	Operating System	Server: Windows Server OS 2022/Windows 11 Pro, 64 bit Client: Windows 11 Pro, 64 bit	Microsoft Windows 11- 64-bit or higher Microsoft Windows 10- 64-bit or higher	Same
9.	DICOM-compliant	Yes	Yes	Same
10.	Software architecture	System is logically broken down into IES PACS and IES viewers subsystems. The IES Viewers further contain the IES_EntViewer, IES_RadViewer and IES_EchoViewer modules.	System that is logically broken down to syngo.via View&GO subsystems. Subsystems are further broken down to syngo modules.	Same
11.	List of Modality support	X-ray Angiograms (XA), Echocardiograms (US), MRI, CT, CR, DR, IVUS, OCT, NM (PET and SPECT).	CT Image (Computed Tomography), MR Image (Magnetic Resonance), NM Image (Nuclear Medicine), XA Image (X-Ray Angiography), US Image (Ultrasound), DX Image (Digital Radiography), DICOM secondary capture objects.	Same
12.	Web Diagnostic Viewer	Standalone software for diagnostic use. Web-based IES ZeroFootPrint Viewer (IES_ZFPViewer) is designed solely for browser-based viewing and is not intended for diagnostic purposes.	Stand-alone software	Same

Sl. No	Features compared	Proposed Device	Reference Predicate Device	Result
13.	Imaging Algorithms used	Multiplanar reconstruction (MPR), Maximum and Minimum Intensity Projection (MIP/MinIP), Basic Volume Rendering with ClipBox, Multimodality registration, automatic spine labeling (no rib labeling), Cardiothoracic Ratio.	Multiplanar reconstruction (MPR), Maximum and Minimum Intensity Projection (MIP/MinIP), Volume Rendering Technique (VRT) with additional edge and surface enhancements and control over rendering parameters, Shaded Surface Display (SSD), Digitally Reconstructed Radiograph, Editor functionality (e.g. ClipBox), Auto-Contour, Registration, Anatomical registration, Region growing, Automatic Spine Labeling, also for ribs in CT thorax scans ("Rib labeling"), Reprocessing X-ray projection images into 3D image and Topograms, FASTAlign, Cinematic VRT1	Same
14.	Quantitative algorithms used	IES_EntViewer: Line Measurement for ECG IES_Radviewer: Distance, Angle, Cobb Angle, ROI IES_EchoViewer: Distance, Angle, Point, Area-MOD (method of disks), VTI (Velocity Time Integral)	Distance, Angle & Angle [1] on-stack, VOI, and ROI Measurement	Similar
15.	Image data Compression	**Receive & Store:** Images are received and stored as received without any change in the compression format. **Display:** Images are displayed as received without any change in the compression. Lossy compression images are displayed with an indication to the user with the compression type (Transfer Syntax) used. **Export:** To DICOM Node: Images are sent as per the DICOM negotiation. Uncompressed is preferred and lossy compression is not supported. To Exchangeable media: Images exported as stored in the local storage.	**Receive & Store:** Images are received and stored as received without any change in the compression format. **Display:** Images are displayed as received without any change in the compression. Lossy compression images are displayed with an indication to the user with the compression ratio. **Export:** To DICOM Node: Images are sent as per the DICOM negotiation. Uncompressed is preferred and lossy compression is not supported. To Exchangeable	Same

Sl. No	Features compared	Proposed Device	Reference Predicate Device	Result
		Supported Compressions for export: • JPEG 2000 Image Compression • JPEG Baseline (Process 1): Default Transfer Syntax for Lossy JPEG 8 Bit Image Compression • JPEG Extended (Process 2 & 4): Default Transfer Syntax for Lossy JPEG 12 Bit Image Compression - (Process 4 only) • JPEG Lossless, Non-Hierarchical (Process 14) • JPEG Lossless, Non-Hierarchical, First-Order Prediction (Process 14 [Selection Value 1]): Default Transfer Syntax for Lossless JPEG Image Compression • JPEG-LS Lossless Image Compression • JPEG-LS Lossy (Near-Lossless) Image Compression • RLE Lossless.	media: Images exported as stored in the local storage. **Supported Compressions for export:** lossless compression algorithms, JPEG, JPEG 2000, and RLE.	
16.	Software self-test / checks	Return valid DICOM error codes to the associated Application Entity in case the data transfer is interrupted. Hardware/Operating System/ Framework Compatibility Check during Installation. Display Compatibility Check supports the end user to qualify the system for hardware-accelerated graphics using a GPU.	Alert the user in case the data transfer is interrupted to the connected DICOM node. Hardware / Operating System compatibility check during Installation. Display Compatibility Check supports the end user to qualify the system for proper diagnostic use.	Same
Software functionalities				
17.	Graphical User Interface	Yes, with text labels, and appropriate tooltips.	Yes, with a reduced color palette, clearer structure, and text labels on icons.	Same
18.	Patient Browser	Yes, with simplified search functionality, Study & series level results, and paging.	Yes, with simplified search functionality, clearer structure of search results, image preview, unlimited search results, and periodic updates of search results.	Same

Sl. No	Features compared	Proposed Device	Reference Predicate Device	Result
19.	Series Navigator	Series-level results can be enabled by the user. Shown in patient worklist with series description.	The Series Navigator lists all currently loaded data within a workflow. Studies are marked with colorized time points.	Same
20.	Findings / Reporting	No findings and reporting support	No, reporting support is provided to create reports using any 3rd party reporting tool. Hence the findings also cannot be navigated.	Same
21.	Imports and exports of data	Import of DICOM data from network nodes or external media, and of DICOM-compliant data from external media and Windows file system. Export to USB, CD/DVD, or other DICOM nodes.	Import of DICOM data from network nodes or external media, and of DICOM-compliant or non-DICOM-compliant data from external media and Windows file system. Export to USB, Windows file system, or other DICOM nodes.	Same
22.	Archiving data	Data stored on IES PACS archive storage.	Data can be sent to an archive if syngo.via View&GO is connected to a PACS or corresponding DICOM node.	Same
23.	Spine/Rib labeling	Yes, with suggested spine labels to be confirmed by the user, and additional smart placement of labels. No rib labeling.	Yes, with suggested spine labels to be confirmed by the user, and additional smart placement of labels, also in inter-vertebra regions, support of 2D images, support of multi-series studies, and added support for rib labels.	Same
24.	Online help system	Context-enabled help for the IES PACS worklist, ENT viewer and ZFP Viewer. User manuals for RadViewer and EchoViewer.	Yes, with a reduced color palette, clearer structure, and text labels on icons	Same
25.	Markers and annotations	Yes, with support for marking a position on an image and textual annotations	Yes, with support for marking a position on an image and textual annotations	Same
26.	Hiding and Showing of Image Overlays	Show or hide graphical objects such as annotations and markers, show or hide reference lines	Show or hide image text, show or hide custom image text, show or hide graphical objects such as annotations and markers, show or hide reference lines, show or hide shutter	Same

VII. NON-CLINICAL PERFORMANCE DATA

The Imagine® Enterprise Suite (IES) is a software platform built on the IES PACS DICOM infrastructure and is based on its predecessor, HCP DICOM Net® PACS (K023467).

The safety and performance of the Imagine® Enterprise Suite have been evaluated and verified against defined software specifications derived from system design documentation, user needs, and risk management activities. These specifications encompass core functionalities, including image acquisition, storage, visualization, segmentation, quantification, user interface behavior, interoperability with PACS systems, and cybersecurity. In addition, performance bench testing was conducted for applicable IES modules in comparison with FDA-cleared predicate devices to demonstrate that safety and performance are not compromised and are comparable to those of the predicate devices.

The IES_EntViewer, IES_EchoViewer, and IES_RadViewer modules do not incorporate deep learning or machine learning-derived outputs and function solely based on deterministic image visualization and measurement capabilities.

In contrast, the IES_AngioQuant module incorporates a machine learning-based coronary vessel segmentation function. Its performance was evaluated using a retrospective, multi-center dataset. An initial assessment was conducted on six deep learning models using predefined metric-based scoring criteria and a visual rating system against ground-truth data. The best-performing model was selected for further training and validation and subsequently evaluated using a comprehensive set of performance metrics, including Jaccard Index (Intersection over Union), Dice Score, Precision, Accuracy, and Recall, in conjunction with visual assessment. Performance was compared against the FDA-cleared predicate device, CAAS Workstation (510(k) No. K232147).

A total of 762 anonymized angiographic studies were used for training, validation, and internal testing, with an independent external test set comprising 30 patient studies. Each sample corresponded to a single patient angiographic study, from which artery-wise segmentation instances were derived. The datasets included adult patients of mixed gender and represented a range of age, body habitus, and diverse race and ethnicity, sourced from multiple U.S. and international clinical sites. Clinically relevant variability—including lesion severity, vessel anatomy, image quality, and imaging equipment vendors—was represented. Images were acquired using mainstream, FDA-cleared angiographic imaging systems under standard coronary angiography protocols.

The reference standard (“truthing”) was established using the FDA-cleared Medis QAngio XA (K182611) software, with verification performed by two independent board-certified interventional cardiologists, each with more than 10 years of clinical experience. Strict separation was maintained between training, validation, internal testing, and external testing datasets to ensure independence of performance evaluation.

Software verification and validation activities were conducted in accordance with applicable FDA guidance and recognized consensus standards. Softlink International Pvt. Ltd. claims conformance with the following guidance documents and standards:

- FDA Guidance, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- IEC 62304:2006 + A1:2015, Medical device software – Software life cycle processes
- ANSI AAMI ISO 14971:2019, Medical devices – Application of risk management to medical devices
- IEC 62366-1:2020, Medical devices – Application of usability engineering to medical devices
- IEC 82304-1:2016, Health software – General requirements for product safety
- NEMA PS 3.1–3.20:2023e, Digital Imaging and Communications in Medicine (DICOM)

VIII. SOFTWARE VERIFICATION AND VALIDATION

Software Verification and Validation (V&V) testing for the Imagine® Enterprise Suite was performed in alignment with the FDA's *Guidance for the Content of Premarket Submissions for Device Software Functions* (June 14, 2023). Based on the potential for a failure or latent software flaw to result in a hazardous situation with a probable risk of death or serious injury to the patient or operator, the software has been classified under the Enhanced Documentation Level. Accordingly, this submission includes comprehensive software documentation consistent with FDA expectations for Enhanced Level of Concern software, encompassing detailed design controls, risk management activities, and validation evidence to demonstrate safe and effective performance.

The Risk Analysis was completed, and risk control was implemented to mitigate identified hazards. The testing results support the claim that all the software specifications met the acceptance criteria. Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

The Imagine® Enterprise Suite complies with the cybersecurity requirements by implementing a process that prevents unauthorized access, modifications, misuse, denial of use, or unauthorized use of information stored, accessed, or transferred from a medical device to an external recipient.

IX. CONCLUSION

The Imagine® Enterprise Suite is built upon the foundation of its predecessor, the HCP DICOM Net® PACS (K023467), with its functionalities restructured into specialized modules: IES_ENT Viewer, IES_EchoViewer, IES_RadViewer, and IES_ZFPViewer that enable more focused and specialized viewing capabilities. Additionally, the module AngioQuant is introduced and supported by two key predicate devices syngo.via View&GO VA40A and MPXA-2000 respectively. A comprehensive comparison of intended use, technological features, device hazards, non-clinical performance data, and software validation confirms that the Imagine® Enterprise Suite (IES) does not introduce any new or significant safety concerns. Based on this, we believe that the device is as safe and effective as its predicate devices and is considered substantially equivalent.