September 15, 2025

Beijing Infervision Healthcare Medical Technology Co., Ltd.
Matt Deng
Official Correspondent
Room B403, 4th Floor, Building 1, No.12, Shangdi Information
Haidian District
Beijing, 100085
China

Re: K250237
Trade/Device Name: InferOperate Suite
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: August 15, 2025
Received: August 15, 2025

Dear Matt Deng:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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
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)*
K250237

Device Name
InferOperate Suite

Indications for Use *(Describe)*
InferOperate Suite is medical imaging software that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning for patients, including both preoperative surgical planning and intraoperative image display. InferOperate Suite accepts DICOM compliant medical images acquired from a variety of imaging devices.
This product is not intended for use with or for the primary diagnostic interpretation of Mammography images.
It provides several categories of tools. It includes basic imaging tools for general images, including 2D viewing, volume rendering and 3D volume viewing, orthogonal Multi-Planar Reconstructions (MPR), surface rendering, measurements, surgical planning, reporting, storing, general image management and administration tools, etc.
It includes a basic image processing workflow and a custom UI to segment anatomical structures. The processing may include the generation of preliminary segmentations of anatomy using software that employs machine learning and other computer vision algorithms, as well as interactive segmentation tools, etc.
InferOperate Suite is designed for use by trained professionals and is intended to assist the clinician who is responsible for making all final patient management decisions.
InferOperate Suite utilizes machine learning-based algorithms for adult patients undergoing CT chest, abdominal, or pelvic scans. For image data of other anatomical regions or modalities, patients under 21 years of age, or patients with unknown age, we provide non-ML software functions, such as STL 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.

510(k) Summary- K250237

InferOperate Suite

Submitter: Beijing Infervision Healthcare Medical Technology Co., Ltd.

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Date Prepared: September 12, 2025

Device Name and Classification

Trade Name:	InferOperate Suite
Common Name:	Automated Radiological Image Processing Software
Classification:	Class II
Regulation Number:	21 CFR 892.2050
Classification Panel:	Radiology
Product Code:	QIH
510(k) Number:	K250237

Predicate Device:

Trade Name:	Visible patient Suite
Manufacturer:	Visible Patient, SAS
Common Name:	system, image processing, radiological
Classification:	Class II
510(k) Number:	K212896
Regulation Number:	21 CFR 892.2050
Classification Panel:	Radiology
Product Code:	LLZ

Device Description

InferOperate Suite is medical imaging software that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning for patients, including both preoperative surgical planning and intraoperative image display. InferOperate Suite receives medical images in DICOM standard format and utilizes machine learning (ML) and other medical image processing techniques, along with interactive segmentation tools, to segment anatomical structures and target ROIs. InferOperate Suite performs 3D reconstruction and visualization, and provides several tools for surgical planning.

The server receives DICOM images, analyzes the images, and provides 3D visualization of the anatomical structures. The system can be deployed on a dedicated on-premise server or a cloud server.

InferOperate Suite provides several categories of tools. It includes basic imaging tools for general image, including 2D viewing, volume rendering and 3D volume viewing, Multi-Planar Reconstructions (MPR), surface rendering, measurements, surgical planning, reporting, storing, general image management and administration tools

Indications for Use

InferOperate Suite is medical imaging software that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning for patients, including both preoperative surgical planning and intraoperative image display. InferOperate Suite accepts DICOM compliant medical images acquired from a variety of imaging devices.

This product is not intended for use with or for the primary diagnostic interpretation of Mammography images.

It provides several categories of tools. It includes basic imaging tools for general images, including 2D viewing, volume rendering and 3D volume viewing, orthogonal Multi-Planar Reconstructions (MPR), surface rendering, measurements, surgical planning, reporting, storing, general image management and administration tools, etc.

It includes a basic image processing workflow and a custom UI to segment anatomical structures. The processing may include the generation of preliminary segmentations of anatomy using software that employs machine learning and other computer vision algorithms, as well as interactive segmentation tools, etc.

InferOperate Suite is designed for use by trained professionals and is intended to assist the clinician who is responsible for making all final patient management decisions.

InferOperate Suite utilizes machine learning-based algorithms for adult patients undergoing CT chest, abdominal, or pelvic scans. For image data of other anatomical regions or modalities, patients under 21 years of age, or patients with unknown age, we provide non-ML software functions, such as STL viewer.

Substantial Equivalence

InferOperate Suite is substantially equivalent in both intended use and technical characteristics to the predicate devices. The variations in design and performance compared to the predicate devices do not impact the safety or effectiveness of InferOperate Suite for its intended use. Table below lists the predicate device alongside the subject device, including their respective Product Codes and Indications for Use.

Detailed Comparison of the Subject and Predicate Devices:

Item	Subject Device: InferOperate Suite	Primary Predicate: Visible Patient Suite (K212896)	Comparison
Product Code	QIH	LLZ	
Classification	Class II	Class II	
Indications for Use	InferOperate Suite is medical imaging software that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning for patients, including both preoperative surgical planning and intraoperative image display. InferOperate Suite accepts DICOM compliant medical images acquired from a variety of imaging devices. This product is not intended for use with or for the primary diagnostic interpretation of Mammography images. It provides several categories of tools. It includes basic imaging tools for general images, including 2D viewing, volume rendering and 3D volume viewing, orthogonal Multi-Planar Reconstructions (MPR), surface rendering, measurements, surgical planning, reporting, storing, general image management	Visible Patient Suite is medical imaging software that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting. and treatment planning for both pediatric and adult patients. Visible Patient Suite accepts DICOM compliant medical images acquired from a variety of imaging devices, including CT, MR. This product is not intended for use with or for the primary diagnostic interpretation of Mammography images. The software provides several categories of tools. It includes basic imaging tools for general images, including 2D viewing, volume rendering and 3D volume viewing. orthogonal Multi-Planar	Same

Item	Subject Device: InferOperate Suite	Primary Predicate: Visible Patient Suite (K212896)	Comparison
	and administration tools, etc. It includes a basic image processing workflow and a custom UI to segment anatomical structures. The processing may include the generation of preliminary segmentations of anatomy using software that employs machine learning and other computer vision algorithms, as well as interactive segmentation tools, etc. InferOperate Suite is designed for use by trained professionals and is intended to assist the clinician who is responsible for making all final patient management decisions. InferOperate Suite utilizes machine learning-based algorithms for adult patients undergoing CT chest, abdominal, or pelvic scans. For image data of other anatomical regions or modalities, patients under 21 years of age, or patients with unknown age, we provide non-ML software functions, such as STL viewer.	Reconstructions (MPR), image fusion, surface rendering. measurements, reporting, storing, general image management and administration tools, etc. It includes a basic image processing workflow and a custom UI to segment anatomical structures, which are visible in the image data (bones, organs, vascular/airway structures. etc.), including interactive segmentation tools, basic image filters, etc. It also includes detection and labeling tools of organ segments (liver, lungs and kidneys), including path definition through vascular/airway, approximation of vascular/airway territories from tubular structures and interactive labeling. The software is designed to be used by trained professionals (including physicians, surgeons and technicians) and is intended to assist the clinician who is solely responsible for making all final patient management decisions.	
Intended User	Trained professionals	Trained professionals	Same
Image Input	DICOM	DICOM	Same
2D viewing	Yes	Yes	Same
3D volume viewing	Yes	Yes	Same

Item	Subject Device: InferOperate Suite	Primary Predicate: Visible Patient Suite (K212896)	Comparison
Orthogonal Multi-Planar Reconstructions (MPR)	Yes	Yes	Same
Surface rendering	Yes	Yes	Same
Measurements	Yes	Yes	Same
Surgical planning	Yes	Yes	Same
Anatomical Region	Thorax, abdomen, pelvis, etc.	Thorax, abdomen, pelvis, etc.	Same
Preoperative viewing of 3D images	Yes	Yes	Same
Intraoperative viewing of 3D images	Yes	Yes	Same
Storing	Yes	Yes	Same
General image data management and administration tools	Yes	Yes	Same
Segmentation	Yes	Yes	Same
Product Availability	Software product	Software product	Same
Modifies the Original DICOM data	No	No	Same

Performance testing:

InferOperate Suite has been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. Additionally, the software validation activities were performed in accordance with IEC 62304 - Medical device software – Software life cycle processes, in addition to the FDA Guidance documents, "Content of Premarket Submissions for Device Software Functions" and "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions."

• Software Verification/Validation Tests
• Performance Tests
• Cybersecurity Testing and Analysis

Segmentation performance was validated on a dataset which was composed of predominantly U.S. subjects. The dataset for performance validation was independent of the training set, with no overlap in data sources.

A total of 188 cases were collected for algorithm performance testing (70 cases of the chest, 61 cases of the abdomen, and 57 cases of the pelvic). The imaging devices mainly included Siemens, GE, Philips and Toshiba, others. Among the chest CT cases, 46 were contrast-enhanced CT scans and the other 24 were non-contrast enhanced CT. All abdominal and pelvic cases were contrast-enhanced CT.

For ground truthing, two Chinese radiologists independently annotated the organs and anatomical structures. Then, an American board-certified radiologist served as an arbitrator. If there were disagreements between the two radiologists' annotations, the arbitrator was responsible for resolving the discrepancies by either selecting the more accurate segmentation as the final ground truth or making any necessary modification as he judged to be accurate. The truthers were independent from algorithm devleopment annotators.

The segmentation performance, characterized by the Dice coefficient (DSC) and 95% Hausdorff Distance (HD95) (mm) is summarized below:

No.	Model	N	Dice			HD95		
			Mean	95%CI	Target	Mean	95%CI	Target
1	Bronchus	70	0.87	0.85-0.88	0.79	2.33	2.07-2.59	3.5
2	Pulmonary artery	70	0.87	0.86-0.88	0.76	3.35	2.79-3.90	5.55
	Pulmonary vein		0.85	0.84-0.86	0.77	3.19	2.96-3.42	5.55
3	Pulmonary lobe	70	0.98	0.97-0.98	0.88	2.63	2.34-2.91	4.15

	Pulmonary segment		0.88	0.88-0.89	0.79	3.42	3.13-3.70	4.15
4	Liver	61	0.98	0.98-0.98	0.87	2.15	2.09-2.22	4.95
5	Hepatic segment (Couinaud's method)	61	0.91	0.89-0.94	0.80	2.54	2.18-2.89	4.95
	Hepatic segment (Vascular method)	61	0.91	0.89-0.94	0.80	3.52	2.90-4.14	4.95
6	Hepatic artery	61	0.89	0.88-0.91	0.80	2.36	1.98-2.74	5.55
7	Hepatic vein	61	0.91	0.90-0.91	0.80	1.86	1.75-1.98	5.55
	Portal vein	61	0.86	0.85-0.86	0.80	2.24	1.65-2.82	5.55
8	Portal vein segment	61	0.85	0.83-0.86	0.75	3.46	2.74-4.18	5.55
9	Gallbladder	56	0.94	0.93-0.96	0.78	2.19	1.74-2.63	3.5
10	Common hepatic-bile duct	61	0.83	0.79-0.88	0.73	3.54	2.05-5.03	5.55
11	Pancreas	61	0.97	0.95-0.98	0.7	2.49	1.23-3.75	10.63
12	Spleen	59	0.97	0.96-0.97	0.84	2.79	1.64-3.94	4.94
13	Kidney	57	0.98	0.98-0.98	0.85	1.79	1.63-2.09	4.86
	Bladder	17	0.98	0.97-0.99	0.80	2.33	0.00-5.33	6.22
14	Renal vein	57	0.86	0.85-0.87	0.80	3.03	2.01-4.13	5.55
15	Renal artery	57	0.85	0.85-0.86	0.80	2.24	2.08-2.76	5.55
16	Upper urinary tract	57	0.84	0.82-0.85	0.70	2.81	2.39-3.53	5.55
17	Adrenal gland	57	0.85	0.82-0.87	0.70	2.69	1.98-3.70	10.63
18	Bone	30	0.97	0.97-0.98	0.80	0.83	0.69-0.97	5.75
19	Skin	30	0.97	0.97-0.98	0.90	0.40	0.32-0.48	10.00

Predetermined Change Control Plan (PCCP)

The InferOperate Suite PCCP outlines two planned modifications to improve ML-based organ segmentation functionality without requiring additional FDA submissions. These include (1) algorithm performance improvement through expansion of the training data, (2) algorithm performance improvement through modification of model architecture, pre/post processing, training methods and parameters. Each proposed change will be implemented according to a

thorough modification protocol and must satisfy rigorous performance standards. This includes demonstrating non-inferiority to the original model; additionally, the performance metric (DICE) must remain above the predetermined performance target values. Established performance assessment and validation protocols will be used. Acceptance criteria must be fulfilled before any model release. All authorized modifications made under the PCCP will be documented and included in the device's labeling as the modifications are released. In accordance with the PCCP, the modified algorithms will be adequately trained, tuned, tested, and locked before release. Implemented modifications to the InferOperate Suite AI algorithms will be communicated to users via the software update notification and through updated labelling.

Conclusion

The InferOperate Suite is substantially equivalent in intended use, design, principles of operation, and safety features to the predicate device. The minor differences in software do not affect its safety and effectiveness. Performance data demonstrates that the InferOperate Suite is as safe and effective as the predicate, and meets its intended use and specifications. Thus, the InferOperate Suite is substantially equivalent.