



July 7, 2026

Beijing Infervision Healthcare Medical Technology Co., Ltd.  
Matt Deng, Primary Contact  
Rm. B403, 4th Floor, Bldg. 1  
#12, Shangdi Information Rd.  
Haidian District, Beijing 100085, China

Re: K260973

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, LLZ  
Dated: [NOTE: Use date of most recent supplement]  
Received: June 4, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink that reads "Jessica Lamb". The signature is written in a cursive style. In the background, there is a large, light blue, semi-transparent watermark of the FDA logo.

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.

K260973

?

Please provide the device trade name(s).

?

InferOperate Suite

Please provide your Indications for Use below.

?

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.

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)

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## 510(k) Summary-K260973

### InferOperate Suite

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

**Address:** Room B403, 4th Floor, Building 1, No.12,  
Shangdi Information Road, Haidian District,  
Beijing 100085, China.  
Phone: +86 10-86462323

**Contact:** Mr. Matt Deng  
Email: matt.deng@infervision.ai  
Phone: 929-335-4879

**Date Prepared:** July 3, 2026

#### Device Name and Classification

**Trade Name:** InferOperate Suite

**Common Name:** Automated Radiological Image Processing Software

**Classification:** Class II

**Regulation Name:** Medical image management and processing system

**Regulation Number:** 21 CFR 892.2050

**Classification Panel:** Radiology

**Product Code:** QIH

#### Predicate Device:

**Trade Name:** InferOperate Suite

**Manufacturer:** Beijing Infervision Healthcare Medical Technology Co., Ltd.

**Common Name:** Automated Radiological Image Processing Software

**Classification:** Class II

**510(k) Number:** K250237

**Regulation Name:** Medical image management and processing system

**Regulation Number:** 21 CFR 892.2050

**Classification Panel:** Radiology

**Product Code:** QIH

## **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**

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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.

## Technological Comparison

The predicate device for this submission is previously cleared FDA 510(k) device, InferOperate Suite (K250237). The subject device, InferOperate Suite, is equivalent to the predicate device in terms of the same device features, indications for use, use environment, input and output data, basic imaging tools, and deep learning algorithms.

The only technological difference between the predicate and subject devices is that the subject device includes an update Predetermined Change Control Plan (PCCP). Similarities of the device with the predicate are maintained following PCCP modifications, and PCCP modifications do not incur additional differences with the predicate device.

### Detailed Comparison of the Subject and Predicate Devices:

| Item                | Subject Device:<br><b>InferOperate Suite</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Predicate Device:<br><b>InferOperate Suite</b><br>(K250237)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Comparison  |
|---------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Product Code        | QIH                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | QIH                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |             |
| Classification      | Class II                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Class II                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Same</b> |
| Manufacturer        | Beijing Infervision Healthcare Medical Technology Co., Ltd.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Beijing Infervision Healthcare Medical Technology Co., Ltd.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <b>Same</b> |
| Indications for Use | <p>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.</p> <p>This product is not intended for use with or for the primary diagnostic interpretation of Mammography images.</p> <p>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.</p> <p>It includes a basic image processing workflow and a custom UI to segment anatomical structures. The processing may include the generation of preliminary</p> | <p>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.</p> <p>This product is not intended for use with or for the primary diagnostic interpretation of Mammography images.</p> <p>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.</p> <p>It includes a basic image processing workflow and a custom UI to segment anatomical structures. The processing may include the generation of preliminary</p> | <b>Same</b> |

| Item                                          | Subject Device:<br><b>InferOperate Suite</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Predicate Device:<br><b>InferOperate Suite</b><br>(K250237)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Comparison              |
|-----------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
|                                               | segmentations of anatomy using software that employs machine learning and other computer vision algorithms, as well as interactive segmentation tools, etc.<br>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. | segmentations of anatomy using software that employs machine learning and other computer vision algorithms, as well as interactive segmentation tools, etc.<br>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. |                         |
| Intended User                                 | Trained healthcare professionals                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Trained healthcare professionals                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Same</b>             |
| Use environment                               | Healthcare facilities such as hospitals and clinics                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Healthcare facilities such as hospitals and clinics                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Same</b>             |
| Product Availability                          | Software product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Software product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Same</b>             |
| Image Input                                   | DICOM                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | DICOM                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>Same</b>             |
| Anatomical Region                             | Thorax, abdomen, pelvis, etc.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Thorax, abdomen, pelvis, etc.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Same</b>             |
| 2D DICOM viewing                              | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Same</b>             |
| 3D viewing                                    | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Same</b>             |
| Orthogonal Multi-Planar Reconstructions (MPR) | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Same</b>             |
| Surface rendering                             | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Same</b>             |
| Measurements                                  | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Same</b>             |
| Measurements for Segmented anatomical part    | Volume, density and diameter.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Volume, density and diameter.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Same</b>             |
| Surgical planning                             | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Same</b>             |
| General image data management                 | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Same</b>             |
| Algorithms of structure                       | deep learning                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | deep learning                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Same Performance</b> |

| Item         | Subject Device:<br><b>InferOperate Suite</b>                                                                                                                                                                                                                                                                                                              | Predicate Device:<br><b>InferOperate Suite</b><br>(K250237)                                                                                                                                                           | Comparison                                               |
|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| Segmentation |                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                       | was validated on a standalone performance testing        |
| PCCP         | (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, (3) Add MR support for existing organs already segmented in CT, (4) expand segmentation algorithm to new organs in CT or MR images. | (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. | <b>Different</b><br>This 510k submits for the extra PCCP |

### 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 development 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<br>(Couinaud's method) | 61 | 0.91 | 0.89-0.94 | 0.80   | 2.54 | 2.18-2.89 | 4.95   |
|     | Hepatic segment (Vascular<br>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 four 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, (3) Add MR support for existing organs already segmented in CT, (4) expand segmentation algorithm to new organs in CT or MR images. 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. Thus, the InferOperate Suite is substantially equivalent.