March 13, 2026

Beijing Infervision Healthcare Medical Technology Co., Ltd.
℅ Matt Deng
Primary Contact
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No.12, Shangdi Information Road, Haidian District
BEIJING, 100085
CHINA

Re: K252261
Trade/Device Name: InferCare RECIST
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: February 12, 2026
Received: February 12, 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
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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)*
K252261

Device Name
InferCare RECIST

Indications for Use *(Describe)*
InferCare RECIST is a post-processing software application used to display, process, analyze, quantify and manipulate multi-time-point CT images. It is intended to be used by trained medical professionals in evaluating and managing tumors in various organs, tissues, and other anatomical structures based on RECIST criteria.

InferCare RECIST offers functionalities for lesion measurement, registration, tracking, and RECIST report. It provides tools for interactive segmentation, and 3D reconstruction visualization.

The software utilizes artificial intelligence algorithms for automated lesion segmentation and registration, and the results require confirmation by a medical professional. The software's artificial intelligence algorithms are intended for patients aged 21 years and older.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary-K252261

InferCare RECIST

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Date Prepared: March 12, 2026

Device Name and Classification

Trade Name:	InferCare RECIST
Classification:	Class II
Common Name:	Automated radiological image processing software
Regulation Name:	Medical image management and processing system
Regulation Number:	21 CFR 892.2050
Classification Panel:	Radiology
Product Code:	QIH

Predicate Device

Trade Name:	Multi-Modality Tumor Tracking (MMTT) application
Manufacturer:	Philips Medical Systems Nederland B.V.
Classification:	Class II
510(k) Number:	K162955
Common Name:	System, image processing, radiological
Regulation Name:	Medical image management and processing system
Regulation Number:	21 CFR 892.2050
Classification Panel:	Radiology
Product Code:	LLZ

Device Description

InferCare RECIST is based on advanced image processing technologies and temporal sequence analysis methods. The software can be installed in a healthcare facility or a cloud-based platform. It ingests medical imaging data compliant with the DICOM standard and supports multi-timepoint image registration. It allows automatic navigation to match lesion locations across different image series based on physician-selected lesions, ensuring accurate tracking and comparison of the same lesion across follow-up studies.

InferCare RECIST integrates machine learning based algorithms to provide interactive segmentation tools, enabling users to generate 3D segmentation and measurement results simply by clicking on the target lesion.

In addition, the system offers a variety of image processing tools, such as window width/level adjustment, multi-planar reconstruction (MPR), and maximum intensity projection (MIP), to meet the needs of different clinical viewing scenarios. Through the integrated use of these technologies, InferCare RECIST delivers accurate lesion measurements, follow-up trend analyses, and RECIST-standard evaluation reports, effectively supporting physicians in making precise diagnostic and treatment decisions.

Indications for Use

InferCare RECIST is a post-processing software application used to display, process, analyze, quantify and manipulate multi-time-point CT images. It is intended to be used by trained medical professionals in evaluating and managing tumors in various organs, tissues, and other anatomical structures based on RECIST criteria.

InferCare RECIST offers functionalities for lesion measurement, registration, tracking, and RECIST report. It provides tools for interactive segmentation, and 3D reconstruction visualization.

The software utilizes artificial intelligence algorithms for automated lesion segmentation and registration, and the results require confirmation by a medical professional. The software's artificial intelligence algorithms are intended for patients aged 21 years and older.

Substantial Equivalence

The subject device is substantially equivalent to the predicate device in the following ways:

Item	**Subject Device: InferCare RECIST**	**Predicate Device: Multi-Modality Tumor Tracking (MMTT) application**	**Comparison**
Application Number	K252261	K162955	-
Product Code	QIH	LLZ	-
Class	Class II	Class II	Same
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	Same

Item	Subject Device: InferCare RECIST	Predicate Device: Multi-Modality Tumor Tracking (MMTT) application	Comparison
Indications for Use/ Intended use	InferCare RECIST is a post-processing software application used to display, process, analyze, quantify and manipulate multi-time-point CT images. It is intended to be used by trained medical professionals in evaluating and managing tumors in various organs, tissues, and other anatomical structures based on RECIST criteria. InferCare RECIST offers functionalities for lesion measurement, registration, tracking, and RECIST report. It provides tools for interactive segmentation, and 3D reconstruction visualization. The software utilizes artificial intelligence algorithms for automated lesion segmentation and registration, and the results require confirmation by a medical professional. The software's artificial intelligence algorithms are intended for patients aged 21 years and older.	Multi-Modality Tumor Tracking (MMTT) application is a post processing software application used to display, process, analyze, quantify and manipulate anatomical and functional images, for CT, MR PET/CT and SPECT/CT images and/or multiple time-points. The MMTT application is intended for use on tumors which are known/confirmed to be pathologically diagnosed cancer. The results obtained may be used as a tool by clinicians in determining the diagnosis of patient disease conditions in various organs, tissues, and other anatomical structures.	Same. Both devices are used for medical image processing to display, process, analyze, quantify, manipulate multi-time-point images and enable RECIST 1.1 categorization.
Intended Users	Radiologists, oncologists, and others trained in reading medical images and applying RECIST criteria	Radiologists, Technologist	Same
Where used	Healthcare facilities such as hospitals and clinics	Healthcare facilities such as hospitals and clinics	Same
Image Input	CT DICOM images	CT, MR, PET/CT and SPECT/CT DICOM images	Similar. The predicate device includes a wider variety

Item	Subject Device: InferCare RECIST	Predicate Device: Multi-Modality Tumor Tracking (MMTT) application	Comparison
			of imaging modalities.
2D DICOM viewing	Yes	Yes	Same
3D Reconstruction	Automatic	Automatic	Same
Multi-Planar Reconstructions (MPR)	Yes	Yes	Same
Registration	Automatic and manual	Automatic and manual	Same
Lesion segmentation	Semi-automatic and manual	Semi-automatic and manual	Same
Segmentation editing tools	Add, Delete, Edit, Undo	Add, Delete, Edit, Undo	Same
Automatic software measurement of segmented lesion	Long axis, short axis, volume, key slice.	Long axis, short axis, volume, key slice, density, etc.	Same
RECIST Report	Yes	Yes	Same
Algorithm characteristics	Artificial Intelligence (AI) algorithm	Traditional algorithm	The algorithm performance of the subject device has been validated through performance testing.

The subject device and the predicate device are substantially equivalent in indications for use, input/output, image registration, and interactive lesion segmentation. Regarding the technical differences between the two devices, standalone performance testing has demonstrated that the subject device meets the predetermined target values.

Performance data

Software verification and validation activities were conducted in accordance with IEC 62304:2006+A1:2015 – Medical device software – Software lifecycle processes and ISO 14971:2019 Medical devices – Application of risk management to medical devices, and in accordance with relevant FDA guidance documents, Guidance for the Content of Premarket Submissions for Device Software Functions (issued June 14, 2023), and Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (issued September 27, 2023).

Cybersecurity and vulnerability analyses were conducted, and it has been determined that InferCare RECIST conforms to the cybersecurity requirements.

The following processes were followed and applied during the design and development of InferCare RECIST:

- Risk Analysis
- Unit Testing
- Integration Testing
- System Testing
- Performance Testing
- Software Verification & Validation
- Cybersecurity Testing and Analysis

Performance of AI algorithm

1. Image Registration Performance Test

   (1) For the primary endpoint: Match Rate, a total of 212 target objects including 184 paired, 21 new and 7 disappeared target objects were annotated as ground truth. Among all 212 pairs, 183 paired, 21 new and 7 disappeared target objects were successfully matched across prior and primary scans by InferCare RECIST. Patient-level bootstrapping: the Match Rate was 0.995 (95% CI: 0.986-1.000), with the lower limit of the 95% C.I. being 0.986.

   (2) For the secondary endpoint: Centroid Error Distance: Patient-level bootstrapping: A total of 183 successfully matched target object pairs in 86 patient-scans were included in the analysis. The MAE of centroid error distance was 2.44mm (95% C.I.: 2.22mm-2.68mm), with the higher limit of the 95% C.I. being 2.68mm.

2. Lesion Segmentation Performance Test

   (1) Segmentation accuracy was set as the primary endpoint, and Long/Short diameter measurement was set as the secondary endpoint. We used the same batch of data to test these two endpoints. The dataset comprises a total of 102 cases, including 42 cases of lung nodules, 23 cases of liver lesions, 23 cases of kidney lesions, and 14 cases of lymph node lesions. The result is listed below:

		Primary endpoint *Segmentation Accuracy*		*Secondary endpoint* *Long/Short Diameter*	
Item	N	Mean (Dice)	95% CI	MAE (%)	95% CI
Lung nodule	42	0.913	0.895-0.932	3.2	2.2-4.2
Liver lesion	23	0.929	0.913-0.944	4.3	3.1-5.5
Kidney lesion	23	0.904	0.889-0.918	4.5	3.3-5.6
Lymph node	14	0.782	0.750-0.814	5.3	3.0-7.6

Conclusion

The InferCare RECIST is substantially equivalent in intended use, main functions, operating principles, and safety features to the predicate device. The minor differences in technological characteristics do not raise different questions of safety or effectiveness. The performance testing reports and the submitted documentations demonstrate that the subject device and the predicate device are substantially equivalent.