July 12, 2024

Hutom Inc.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
18881 Von Karman Ave. STE 160
IRVINE CA 92612

Re: K233457
Trade/Device Name: RUS
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: June 14, 2024
Received: June 14, 2024

Dear Priscilla Chung:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

, for

Jessica Lamb
Assistant Director
DHT8B: Division of Radiologic 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)*
K233457

Device Name
RUS

Indications for Use *(Describe)*
RUS 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. RUS accepts DICOM compliant medical images acquired from iodine contrast-enhanced abdomen CT.

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, 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 structures, etc.), including interactive segmentation tools, basic image filters, etc.

It also includes detection and labeling tools of organ segments, including path definition through vascular 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.

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

(K233457)

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

1. **Date:** 06/13/2024

2. **Applicant / Submitter**

Hutom Inc.
6F, 279, Dongmak-ro, Mapo-gu, Seoul
Republic of Korea

3. **U.S. Designated Agent**

Priscilla Chung
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18881 Von Karman Ave. STE 160
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Tel: 714.202.5789 Fax: 714.409.3357
Email: juhee.c@LKconsultingGroup.com

4. **Device Information:**

- Trade/Device Name: RUS
- Common Name: Automated Radiological Image Processing Software
- Regulation Name: Medical image management and processing system
- Regulation Number: 21 CFR 892.2050
- Regulatory Class: II
- Product Code: QIH

5. **Predicate Device:**

- Primary Predicate Device: Visible patient Suite (K212896) by Visible Patient, SAS
- Reference Predicate Device: Synapse 3D Base Tools v6.6 (K221677) by FUJIFILM Corporation

6. **Device Description:**

RUS uses DICOM (Digital Imaging and Communications in Medicine) standards to analyze CT images. This software provides trained medical professionals with tools to aid them in

reading, interpreting, reporting, and treatment planning. By observing the medical images standard protocol (DICOM standards), this software can receive transmitted images from medical imaging devices through the h-Server and can be interfaced with PACS (Picture Archiving and Communication System).
RUS allows surgical planning by 3D modeling from patient's CT data. Surgical planning in RUS does not replace actual surgery and can only be used as an auxiliary tool.
CT is taken at the hospital, the patient's CT data is obtained from PACS, and the CT data is transferred from PACS to h-Server. When CT data and patient information are registered in the h-Server, the data is pseudonymized and anonymized and safely moved to the h-Space. If you request hu3D production by registering CT data and patient information through h-Server, hu3D will be provided within 72 hours. Then you may download the hu3D model through RUS Stomach Planning and perform Surgical planning.

RUS is a software suite and includes three software components: h-Server, h-Space, and RUS Stomach Planning.

1) h-Server
h-Server includes modules dedicated to data management and data gateway. The software is a simple tool either to anonymize or pseudonymize multidimensional digital images acquired from a variety of medical imaging modalities (DICOM images). There is no 3D data volume interpretation in this software.

2) h-Space
h-Space includes data management (except for DICOM files anonymization/pseudonymization module) and 3D reconstruction. This software offers a flexible solution to help trained medical professionals with image processing knowledge (usually radiologists or radiologist technicians) in (1) the evaluation of patient's anatomy, and (2) in the creation of a 3D model of the patient's anatomy. This software proposes flexible workflow options: visualization of patient's anatomy from medical images; creation a 3D model of the patient's anatomical structures, organ segments and volumetric data; creation of an anatomical atlas (a colored image where each color represents a structure); and exports these medical data to be analyzed or reviewed later.

3) RUS Stomach Planning
RUS Stomach Planning includes modules dedicated to patient & data management and surgical planning. This software offers a flexible visualization solution to help trained medical professionals (clinicians) in the evaluation of patient's anatomy to plan therapy or surgery.

7. Indication for use:

RUS 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. RUS accepts DICOM compliant medical images acquired from iodine contrast-enhanced abdomen CT.

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, 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 structures, etc.), including interactive segmentation tools, basic image filters, etc.

It also includes detection and labeling tools of organ segments, including path definition through vascular 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.

8. Substantial Equivalence:

The RUS is substantially equivalent to the following predicate devices:

- Primary Predicate Device: Visible Patient Suite (K212896) by Visible Patient, SAS
- Reference Device: Synapse 3D Base Tools v6.6 (K221677) by FUJIFILM Corporation

8.1.Comparison Chart

Elements of Comparison	Subject Device	Primary Predicate	Additional Predicate	Comparison
Device Name	RUS	Visible patient Suite	Synapse 3D Base Tools v6.6	
510#	K233457	K212896	K221677	
Manufacturer	Hutom	Visible Patient, SAS	FUJIFILM Corporation	
Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological	System, Image Processing, Radiological	Same
Regulation Number No.	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050	Same
Product Code	QIH	LLZ	LLZ	Same
Classification	Class II	Class II	Class II	Same
Indications for use	RUS 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. RUS accepts DICOM compliant medical images acquired from iodine contrast-enhanced abdomen CT. This product is not intended for use with or for the primary diagnostic interpretation of Mammography	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	Synapse 3D Base Tools is medical imaging software that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning. Synapse 3D Base Tools accepts DICOM compliant medical images acquired from a variety of imaging devices including, CT, MR, CR, US, NM, PT, and XA, etc. This product is not intended for use with or for the primary diagnostic	Same

Elements of Comparison	Subject Device	Primary Predicate	Additional Predicate	Comparison
	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, 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 structures, etc.), including interactive segmentation tools, basic image filters, etc. It also includes detection and labeling tools of organ segments, including path definition through vascular 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.	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 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	interpretation of Mammography images. Synapse 3D Base Tools provides several levels of tools to the user: Basic imaging tools for general images, including 2D viewing, volume rendering and 3D volume viewing, orthogonal/ oblique/ curved Multi-Planar Reconstructions (MPR), Maximum (MIP), Average (RaySum) and Minimum (MinIP) Intensity Projection, 4D volume viewing, image fusion, image subtraction, surface rendering, sector and rectangular shape MPR image viewing, MPR for dental images, creating and displaying multiple MPR images along an object, time-density distribution, basic image processing, noise reduction, CINE, measurements, annotations, reporting, printing, storing, distribution, and general image management and administration tools, etc. -Tools for regional segmentation of anatomical structures within the image data, path definition through vascular and other tubular structures, and boundary detection. -Image viewing tools for modality specific images, including CT PET fusion and ADC image viewing for MR studies.	

Elements of Comparison	Subject Device	Primary Predicate	Additional Predicate	Comparison
		all final patient management decisions.	-Imaging tools for CT images including virtual endoscopic viewing and dual energy image viewing. -Imaging tools for MR images including delayed enhancement image viewing, diffusion-weighted MRI image viewing.	
Intended user	Trained professionals (including physicians, surgeons and technicians)	Trained professionals (including physicians, surgeons and technicians)	Trained medical professionals	Same
Where used	Hospital	Hospital	Hospital	Same
Type of input data	CT	CT, MR	CT, MR, CR, US, NM, PT, and XA, etc	Same
Data information processing	Anonymization (Some Dicom Tag) Pseudonymization (Patient name, ID)	Anonymization (DICOM data, patient information)	Anonymization (Patient name, ID, study list)	Similar
2D viewing	YES	YES	YES	Same
Image Storing (DICOM SCP)	YES	YES	YES	Same
Image Communication (DICOM SCU)	YES	YES	YES	Same
Printing (DICOM SCU)	YES	YES	YES	Same
Measurements (2D and 3D)	YES	YES	YES	Same
Reporting	YES	YES	YES	Same
Volume Rendering and 3D viewing	YES	YES	YES	Same
Image fusion	YES	YES	YES	Same
Surface fusion	YES	YES	YES	Same
Image subtraction (3D)	YES	YES	YES	Same

Elements of Comparison	Subject Device	Primary Predicate	Additional Predicate	Comparison
General image data management and administration tools	YES	YES	YES	Same
Segmentation	YES	YES	YES	Same
Virtual Endoscopic Simulator	YES	No	YES	Same
Product Availability	Software product	Software product	Software product	Same
Hardware platform	Windows PC	Windows PC	Windows PC	Same

8.2. Substantial Equivalence Discussion

The Substantial Equivalence (SE) Comparison Table (Table 8.1) in which we compare the differences and similarities of the proposed device to the predicate device follows in this Section and the reference device is only similar with function (tool) compared with the subject device.
The subject device is substantially equivalent to the predicate device in the following ways:

- Indications for Use
  The subject device has the same indications for use as the predicate devices.

- Where used
  The subject device shares the same usage environment as the predicate device.

- Type of input data
  The input data for the subject device consists of CT images, which is consistent with the input data type of the predicate device.

- Basic imaging tools

The fundamental imaging tools, such as 2D/3D viewing, image storage, communication, printing, reporting, and rendering, are identical to those of the predicate device. These tools are part of the existing toolkit of the predicate device.

- Segmentation
  The application segments and reconstructs various anatomical structures including organs (such as the liver, stomach, spleen, gallbladder, and pancreas), vessels, and skin. The predicate devices' segmentation areas encompass those of the subject device. The subject device has similar or different technical characteristics to the predicate devices in the following ways:

- Technological characteristics
  The RUS has the same principles of operation as its predicate device, but there are some differences in technical characteristics. There is a difference between anonymization and pseudonymization in data information processing. While the predicate devices anonymize DICOM data and patient information (such as ID and name), the subject device pseudonymizes patient names and IDs while also anonymizing certain DICOM tags. The validation test has confirmed the effectiveness of this data information processing. This difference does not raise a new concern in safety or effectiveness.

The subject device, RUS, is equivalent to the predicate device in terms of the same indications for use, intended user, target population, use environment, type of input data, and basic imaging tools. Performance tests were carried out to assess the functionality of RUS, the subject device. The test results of all conducted tests support that the subject device is substantially equivalent to the predicate device.

9. Performance Data:

Safety and performance of RUS 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 62304:2006/Amd 1: 2015- Medical device software – Software life cycle processes, in addition to the FDA Guidance documents, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "Content of Premarket Submission for Management of Cybersecurity in Medical Devices."

- Software Verification/Validation Tests
- Performance Tests (Segmentation Accuracy, pneumoperitoneum, Length Measurement)

Three machine learning models are included in RUS. (Organ: CADD U-NET, Vessel: 3D U-NET, Pneumoperitoneum: Linear regression). These models were verified with datasets of actual CT imaging studies of patients. A total of 60 imaging studies were used to evaluated the device. No dataset contained more than one imaging study from any particular patient. No imaging study used to verify performance was used for training; independence of training and testing data were enforced at the level of the scanning institution, namely, studies sourced from a specific institution were used for either training or testing but could not be used for both. The data used in the device validation ensured diversity in patient population and CT system manufacturer. The data acquired from different CT systems and acquisition condition to reflect the intended use environment and the recommended CT settings. The data includes patients with and without disease.

Performance was verified by comparing segmentations and pneumoperitoneum generated by the machine learning models against segmentations generated by medical professionals and 3D scan data form the same imaging study.

h-Space is divided into Organ, Vessel, and Pneumoperitoneum, and the target performance is described. For Organ Segmentation, the target performance is set DSC 0.920 by referring and literature on Multi-Organ Segmentation.[1] According to the literature, using various methods to calculate the DSC results for multiple organ segmentations yielded a maximum average value of 0.918. Therefore, to set a higher target, we referred to relevant papers and established criteria of organ segmentation at 0.920.
For Vessel Segmentation, we set a target performance of DSC 0.890 by referring to the literature.[2] This literature describes a framework for vessel segmentation. It reports cases of achieving high DSC on vessel data, making it a valuable resource for establishing benchmarks for vessel segmentation. Among the various structures' vessel segmentation scores, we set the highest value of 0.890 as our criteria.
For Pneumoperitoneum, the target performance was set to MAE ± 1.083mm based on the

1 Yucheng Tang, Dong Yang, Wenqi Li, Holger Roth, Bennett Landman, Daguang Xu, Vishwesh Nath, Ali Hatamizadeh (2022, March). Self-Supervised Pre-Training of Swin Transformers for 3D Medical Image Analysis. arXiv:2111.14791v2 from https://doi.org/10.48550/arXiv.2111.14791

2 Giles Tetteh, Velizar Efremov, Nils D. Forkert, Matthias Schneider, Jan Kirschke, Bruno Weber, Claus Zimmer, Marie Piraud and Björn H. Menze (2020, Dec). DeepVesselNet: Vessel Segmentation, Centerline Prediction, and Bifurcation Detection in 3D Angiographic Volumes. from https://doi.org/10.3389/fnins.2020.592352

validation data during the model development process.

The performance of the machine learning models, characterized by the Dice coefficient Scores (DSC) and Mean Absolute Error (MEA), was as follows: Organ 0.927 DSC; Vessel 0.920 DSC; Pneumoperitoneum +/- 0.972 mm;

The accuracy of length measurement features has been validated on phantom data and hu3D data. The type of measurements verified were distances between two points (Ruler function). The measurements produced by RUS were verified to be accurate within a mean difference of +/- 10%.

10. Conclusion:

The subject device is substantially equivalent in the areas of technical characteristics, general function, application, and indications for use. The test results also support the substantial equivalence to the predicate devices. Therefore, we conclude that the subject device described in this submission is substantially equivalent to the predicate device.