October 27, 2023

MeVis Medical Solutions AG
Rolf Rzodeczko
Manager Regulatory Affairs
Caroline-Herschel-Strasse 1
BREMEN, BREMEN 28359
GERMANY

Re: K232045
Trade/Device Name: MeVis Liver Suite
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: September 27, 2023
Received: September 27, 2023

Dear Rolf Rzodeczko:

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,

Digitally signed by Gabriela M. Rodal -S for

Lu Jiang, Ph.D.
Assistant Director
DHT8B: Division of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232045

Device Name
MeVis Liver Suite

Indications for Use *(Describe)*
MeVis Liver Suite is an image analysis software and intended to be used for visualization of hepatic imaging studies derived from CT and MR scanning devices (image source: single- and multiframe DICOM).

MeVis Liver Suite supports physicians in their workflow for evaluating the liver, related vascular anatomy, and the volume of liver and liver vascular territories for treatment planning, preoperative evaluation of surgery strategies, and post-procedure or therapy follow-up assessment of the hepatic system and related vascular structures.

MeVis Liver Suite supports image analysis for multiphase contrast enhanced CT, dynamic contrast enhanced MRI, and MRCP. MeVis Liver Suite only allows import of homogenous image series (i.e., image and pixel size must be constant within each series) and with orthogonal image matrix (without a gantry tilt). Images with a resolution of > 5mm slice spacing are not suitable for image analysis with MeVis Liver Suite.

MeVis Liver Suite can be used for manual segmentation, user-defined manual labeling, and 3D visualization of:
- abdominal organs (i.e., liver, stomach, duodenum, spleen, kidney, gallbladder, and pancreas)
- liver related vascular structures (i.e., bile ducts, hepatic artery, hepatic vein, portal vein, and inferior vena cava)
- lesions inside and adjacent to the liver

The tools for manual segmentation and 3D visualization are applicable for CT and MR imaging studies.
In addition to the manual segmentation tools, MeVis Liver Suite provides AI based semi-automatic pre-segmentation tools for liver, hepatic artery, hepatic vein, and portal vein restricted to CT scans of potential living liver donors with healthy livers and intended for:
- Liver: contrast enhanced late-venous and venous phase
- Hepatic vein: contrast enhanced late-venous and venous phase
- Portal vein: contrast enhanced late-venous and venous phase
- Hepatic artery: contrast enhanced arterial phase

Using MeVis Liver Suite, users can evaluate the segmented objects by exploring, calculating, and manually correcting:
- the volume of the segmented abdominal organs (see above)
- the volume of the segmented lesions inside and adjacent to the liver
- the volume of the manually defined parts of the liver
  - by defining separation planes (“separation proposals”)
  - from vascular territories that are derived from the user-defined labeling of the liver related vascular structures
- 3D visualizations of user-defined (vascular) tumor margins (coloring of area - based on user-defined margin sizes/ distances - between the edges of user-defined lesions in relation to the edges of user-defined vascular structures of the liver)
- based on user provided values, calculation of liver volume to body weight ratios (i.e., estimated weight for remnant or graft, body surface area, graft to recipient body weight ratio, graft to SLV ratio, remnant to body weight ratio).

Using a manual spatial registration of the images, the segmented objects (created on different CT phases and MRI sequences) can be visualized together.

The information created with MeVis Liver Suite is intended to be used only in addition to the original images, clinical data, and the real anatomical and clinical situation. Physicians make all final patient management, assessment, and treatment decisions.
MeVis Liver Suite is not intended for the anatomical systems integumentary, skeletal, muscular, lymphatic, respiratory, nervous, reproductive, and cardiovascular (excluding hepatic).
MeVis Liver Suite does not support the following application areas: real time viewing, diagnostic review, image manipulation, optimization, virtual colonoscopy, and automatic lesion detection.
MeVis Liver Suite does not utilize high-resolution displays or display drivers and should not be used as a replacement for a PACS workstation.

Intended Patient Population:
The intended patients for MeVis Liver Suite are oncologic patients or hepatic donor/transplant patients. CT or MR imaging with contrast agents need to be possible for analysis of vascular structures inside the liver. The age group for the intended patient population is 18 or older.
In addition, the semi-automatic pre-segmentation tools are restricted to CT scans of potential living liver donors with healthy livers.

Intended Part of the Body:
Images supported for the intended medical indication include the abdominal body part with the liver and related vascular structures (bile ducts, hepatic artery, hepatic vein, portal vein, inferior vena cava).

Intended User Profile:
The intended users are radiologists and surgeons.

Intended Use Environment:
The use environment is expected to be in an office environment under typical office conditions in hospitals or medical practices.

Operation Principle:
The software acts as modality for display of CT or MR imaging data, and for visualization of the image analysis results on a computer system. MeVis Liver Suite does not come into direct contact or indirect contact with patients or other medical devices.

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.

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MeVis

K232045 510(k) Summary

1 Submitter

Submitted Name: MeVis Medical Solutions AG
Caroline-Herschel-Straße 1
28359 Bremen
Germany

Establishment Name: MeVis Medical Solutions AG

Establishment Registration Number: 3010601176

Date Prepared: 07/10/2023

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2 Device

Device Trade Name: MeVis Liver Suite

Device Common Name: MeVis Liver Suite

Regulation: 21 CFR 892.1750

Classification Name: Computed tomography x-ray system

Product Code: JAK

Class: Class II

Panel: Radiology

3 Primary Predicate Device

510(k) Number	Primary Predicate Device	Product Code
K133643	syngo.CT Liver Analysis	JAK

4 Secondary Predicate Device(s)

510(k) Number	Secondary Predicate Device	Product Code
K173420	Radiomics App v1.0	LLZ

5 Reference Device[1]

510(k) Number	Reference Device	Product Code
K193562	AI-Rad Companion Organs RT	QKB

6 Device Description

MeVis Liver Suite is an image analysis software and intended to be used for visualization of hepatic imaging studies derived from CT and MR scanning devices (image source: single- and multiframe DICOM).

MeVis Liver Suite supports physicians in their workflow for evaluating the liver, related vascular anatomy, and the volume of liver and liver vascular territories for treatment planning, preoperative evaluation of surgery strategies, and post-procedure or therapy follow-up assessment of the hepatic system and related vascular structures.

The information created with MeVis Liver Suite is intended to be used only in addition to the original images, clinical data, and the real anatomical and clinical situation. Physicians make all final patient management, assessment, and treatment decisions.

Software and Operating System
MeVis Liver Suite is a standalone software application that can be installed on any PC that runs on Windows 10 which meet the hardware requirements.

Supported Modalities
DICOM compatible CT and MR image data with or without contrast.
The tools for manual segmentation and 3D visualization (see below) are applicable for CT and MR image data with the exception of the AI based semi-automatic pre-segmentation tools. The

[1] Reference device for liver AI pre-segmentation performance acceptance criteria

semi-automatic pre-segmentation tools are restricted to CT scans of potential living liver donors with healthy livers.

Image import and selection
MeVis Liver Suite supports image analysis for multiphase contrast enhanced CT, dynamic contrast enhanced MRI, and MRCP. MeVis Liver Suite only allows import of homogenous image series (i.e., image and pixel size must be constant within each series) and with orthogonal image matrix (without a gantry tilt). Images with a resolution of > 5mm slice spacing are not suitable for image analysis with MeVis Liver Suite.

MeVis Liver Suite can be used to manually select DICOM images (CT and MR) for import.
The user can visually inspect the images, if the anatomical structures are visible and if the image resolution and image quality is acceptable for the manual segmentation and the user's needs.

Segmentation and 3D visualization
MeVis Liver Suite provides multiple contouring tools for manual segmentation.
The user has full control over the workflow and decides which structures to segment. 3D visualizations are created on demand. The following segmentation workflows are available:

- **Abdominal organs**
  MeVis Liver Suite is intended to be used to manually segment and visualize liver, stomach, duodenum, spleen, kidney, gallbladder, or pancreas using contouring tools. Users can inspect and manually correct, add, and delete their segmentation until they are satisfied with the result. The following tools are available:
    - Freehand contouring
    - Region Growing
- **Liver related vascular structures**
  MeVis Liver Suite is intended to be used to manually segment and visualize bile ducts, hepatic artery, hepatic vein, portal vein, and inferior vena cava, including the option to manually classify different vessels of the vascular branches by assigning them user-defined labels. Users can inspect and manually correct, add, and delete their segmentation until they are satisfied with the result. The following tools are available:
    - Freehand drawing and freehand contouring
    - Region Growing
    - Edit and label 3D tree
- **Lesions inside and adjacent to the liver**
  MeVis Liver Suite is intended to be used to manually segment, visualize, and label user identified lesions inside and adjacent to the liver using:
    - Freehand contouring

  MeVis Liver Suite does not identify or highlight lesions or other abnormalities.

Additionally, the user can use **AI based semi-automatic pre-segmentation** of **liver** and **liver related vascular structures** to create a segmentation proposal. The semi-automatic pre-segmentation uses locked/non adaptive AI networks.

- **Semi-automatic pre-segmentation of the liver**
    - Supported modalities
        - CT, contrast enhanced late-venous and venous phase
    - Limitations
        - Only intended for living donor liver transplantation cases (healthy livers)
- **Semi-automatic pre-segmentation for liver related vascular structures**

- Supported modalities
  - Hepatic vein: CT, contrast enhanced late-venous and venous phase
  - Portal vein: CT, contrast enhanced late-venous and venous phase
  - Hepatic artery: CT, contrast enhanced arterial phase
- Limitations
  - Only intended for living donor liver transplantation cases (healthy livers)

Evaluation of segmented objects
Users can evaluate the segmented objects by exploring, calculating, and manually correcting:

- **Volume**
  MeVis Liver Suite calculates the volume (via voxel-counting of segmentation mask) and displays the volume information to the user for the following manually segmented objects:
  - Abdominal organs (i.e., liver, stomach, duodenum, spleen, kidney, gallbladder, pancreas)
  - Lesions inside and adjacent to the liver
  - Manually defined parts of the liver
    - "Separation proposals"
      The user can manually define separation planes that part the liver into virtual parts. The user manually labels the parts as either "resection"/"graft" (for coloring the 3D visualization of the user-defined part with a red color), or "remnant" (green color)
    - "Vascular territories"
      Using the user-defined labeling (name and color) of vessel subtrees, the software calculates segmentation masks for the corresponding vascular territories within the liver
- **3D visualizations of user-defined (vascular) tumor margins** (coloring of area - based on user-defined margin sizes/distances - between the edges of user-defined lesions in relation to the edges of user-defined vascular structures of the liver)
  - The distance of vascular structures to user selected lesions can be visualized with colored 3D visualizations:
    - with color coded vascular structures ("vascular tumor margins")
    - with color coded voxels around a lesion inside the liver ("tumor margins")
- **Based on user provided values, calculation of liver volume to body weight ratios**
  MeVis Liver Suite provides the following calculations:
  - Estimated Weight for Remnant and Graft
  - Body Surface Area
  - Graft to Recipient Body Weight Ratio
  - Graft to Standard Liver Volume (SLV) Ratio
  - Remnant Volume to Body Weight Ratio

Manual spatial registration
MeVis Liver Suite supports performing a manual spatial registration of the images from different modalities and studies (CT and MR). The user can manually align the imported images visually in pairs on top of each other using manual rigid registration.

Reporting
Using MeVis Liver Suite, the user can report results of the image analysis in different formats (DICOM for archiving, with DICOM definitions for 2D segmentation and 3D volumes; HTML report).

7 Indications for Use

MeVis Liver Suite is an image analysis software and intended to be used for visualization of hepatic imaging studies derived from CT and MR scanning devices (image source: single- and multiframe DICOM).

MeVis Liver Suite supports physicians in their workflow for evaluating the liver, related vascular anatomy, and the volume of liver and liver vascular territories for treatment planning, preoperative evaluation of surgery strategies, and post-procedure or therapy follow-up assessment of the hepatic system and related vascular structures.

MeVis Liver Suite supports image analysis for multiphase contrast enhanced CT, dynamic contrast enhanced MRI, and MRCP. MeVis Liver Suite only allows import of homogenous image series (i.e., image and pixel size must be constant within each series) and with orthogonal image matrix (without a gantry tilt). Images with a resolution of > 5mm slice spacing are not suitable for image analysis with MeVis Liver Suite.

MeVis Liver Suite can be used for manual segmentation, user-defined manual labeling, and 3D visualization of:

- abdominal organs (i.e., liver, stomach, duodenum, spleen, kidney, gallbladder, and pancreas).
- liver related vascular structures (i.e., bile ducts, hepatic artery, hepatic vein, portal vein, and inferior vena cava)
- lesions inside and adjacent to the liver

The tools for manual segmentation and 3D visualization are applicable for CT and MR imaging studies.
In addition to the manual segmentation tools, MeVis Liver Suite provides AI based semi-automatic pre-segmentation tools for liver, hepatic artery, hepatic vein, and portal vein restricted to CT scans of potential living liver donors with healthy livers and intended for:

- Liver: contrast enhanced late-venous and venous phase
- Hepatic vein: contrast enhanced late-venous and venous phase
- Portal vein: contrast enhanced late-venous and venous phase
- Hepatic artery: contrast enhanced arterial phase

Using MeVis Liver Suite, users can evaluate the segmented objects by exploring, calculating, and manually correcting:

- the volume of the segmented abdominal organs (see above)
- the volume of the segmented lesions inside and adjacent to the liver
- the volume of the manually defined parts of the liver
    - by defining separation planes (“separation proposals”)
    - from vascular territories that are derived from the user-defined labeling of the liver related vascular structures
- 3D visualizations of user-defined (vascular) tumor margins (coloring of area - based on user-defined margin sizes/distances - between the edges of user-defined lesions in relation to the edges of user-defined vascular structures of the liver)
- based on user provided values, calculation of liver volume to body weight ratios (i.e., estimated weight for remnant or graft, body surface area, graft to recipient body weight ratio, graft to SLV ratio, remnant to body weight ratio).

Using a manual spatial registration of the images, the segmented objects (created on different CT phases and MRI sequences) can be visualized together.

The information created with MeVis Liver Suite is intended to be used only in addition to the original images, clinical data, and the real anatomical and clinical situation. Physicians make all final patient management, assessment, and treatment decisions.
MeVis Liver Suite is not intended for the anatomical systems integumentary, skeletal, muscular, lymphatic, respiratory, nervous, reproductive, and cardiovascular (excluding hepatic).
MeVis Liver Suite does not support the following application areas: real time viewing, diagnostic review, image manipulation, optimization, virtual colonoscopy, and automatic lesion detection.
MeVis Liver Suite does not utilize high-resolution displays or display drivers and should not be used as a replacement for a PACS workstation.

Intended Patient Population:
The intended patients for MeVis Liver Suite are oncologic patients or hepatic donor/transplant patients. CT or MR imaging with contrast agents need to be possible for analysis of vascular structures inside the liver. The age group for the intended patient population is 18 or older.
In addition, the semi-automatic pre-segmentation tools are restricted to CT scans of potential living liver donors with healthy livers.

Intended Part of the Body:
Images supported for the intended medical indication include the abdominal body part with the liver and related vascular structures (bile ducts, hepatic artery, hepatic vein, portal vein, inferior vena cava).

Intended User Profile:
The intended users are radiologists and surgeons.

Intended Use Environment:
The use environment is expected to be in an office environment under typical office conditions in hospitals or medical practices.

Operation Principle:
The software acts as modality for display of CT or MR imaging data, and for visualization of the image analysis results on a computer system. MeVis Liver Suite does not come into direct contact or indirect contact with patients or other medical devices.

8 Technological Characteristics Comparison

The design, function, and specifications of MeVis Liver Suite are similar to the identified legally marketed primary predicate and secondary predicate device. The MeVis Liver Suite software combines functionalities of the predicate devices. MeVis Liver Suite allows the medical professionals to display DICOM CT and MR images, and to do a segmentation of internal structures of interest as organs, lesions, vascular structures, including functionality of automatic pre-segmentation that supports the clinicians for contouring.
From a functionality point of view, MeVis Liver Suite and the combination of the predicate devices are substantially equivalent and they cover the same (combined) intended use.

Key differences in design and performance between MeVis Liver suite and the predicate devices are solely on a technical level.

Table 1 Comparison table for indications for use.

Device	Indications for Use

Subject Device MeVis Liver Suite	MeVis Liver Suite is an image analysis software and intended to be used for visualization of hepatic imaging studies derived from CT and MR scanning devices (image source: single- and multiframe DICOM).
	
	MeVis Liver Suite supports physicians in their workflow for evaluating the liver, related vascular anatomy, and the volume of liver and liver vascular territories for treatment planning, preoperative evaluation of surgery strategies, and post-procedure or therapy follow-up assessment of the hepatic system and related vascular structures.
	
	MeVis Liver Suite supports image analysis for multiphase contrast enhanced CT, dynamic contrast enhanced MRI, and MRCP. MeVis Liver Suite only allows import of homogenous image series (i.e., image and pixel size must be constant within each series) and with orthogonal image matrix (without a gantry tilt). Images with a resolution of > 5mm slice spacing are not suitable for image analysis with MeVis Liver Suite.
	
	MeVis Liver Suite can be used for manual segmentation, user-defined manual labeling, and 3D visualization of:
	• abdominal organs (i.e., liver, stomach, duodenum, spleen, kidney, gallbladder, and pancreas).
	• liver related vascular structures (i.e., bile ducts, hepatic artery, hepatic vein, portal vein, and inferior vena cava)
	• lesions inside and adjacent to the liver
	The tools for manual segmentation and 3D visualization are applicable for CT and MR imaging studies.
	In addition to the manual segmentation tools, MeVis Liver Suite provides AI based semi-automatic pre-segmentation tools for liver, hepatic artery, hepatic vein, and portal vein restricted to CT scans of potential living liver donors with healthy livers and intended for:
	• Liver: contrast enhanced late-venous and venous phase
	• Hepatic vein: contrast enhanced late-venous and venous phase
	• Portal vein: contrast enhanced late-venous and venous phase
	• Hepatic artery: contrast enhanced arterial phase
	
	Using MeVis Liver Suite, users can evaluate the segmented objects by exploring, calculating, and manually correcting:
	• the volume of the segmented abdominal organs (see above)
	• the volume of the segmented lesions inside and adjacent to the liver
	• the volume of the manually defined parts of the liver
	  ○ by defining separation planes (“separation proposals”)
	  ○ from vascular territories that are derived from the user-defined labeling of the liver related vascular structures
	• 3D visualizations of user-defined (vascular) tumor margins (coloring of area - based on user-defined margin sizes/distances - between the edges of user-defined lesions in relation to the edges of user-defined vascular structures of the liver)
	• based on user provided values, calculation of liver volume to body weight ratios (i.e., estimated weight for remnant or graft, body surface area, graft to recipient body weight ratio, graft to SLV ratio, remnant to body weight ratio).
	
	Using a manual spatial registration of the images, the segmented objects (created on different CT phases and MRI sequences) can be visualized together.
	
	The information created with MeVis Liver Suite is intended to be used only in addition to the original images, clinical data, and the real anatomical and clinical situation. Physicians make all final patient management, assessment, and treatment decisions.

	MeVis Liver Suite is not intended for the anatomical systems integumentary, skeletal, muscular, lymphatic, respiratory, nervous, reproductive, and cardiovascular (excluding hepatic). MeVis Liver Suite does not support the following application areas: real time viewing, diagnostic review, image manipulation, optimization, virtual colonoscopy, and automatic lesion detection. MeVis Liver Suite does not utilize high-resolution displays or display drivers and should not be used as a replacement for a PACS workstation. Intended Patient Population: The intended patients for MeVis Liver Suite are oncologic patients or hepatic donor/transplant patients. CT or MR imaging with contrast agents need to be possible for analysis of vascular structures inside the liver. The age group for the intended patient population is 18 or older. In addition, the semi-automatic pre-segmentation tools are restricted to CT scans of potential living liver donors with healthy livers. Intended Part of the Body: Images supported for the intended medical indication include the abdominal body part with the liver and related vascular structures (bile ducts, hepatic artery, hepatic vein, portal vein, inferior vena cava). Intended User Profile: The intended users are radiologists and surgeons. Intended Use Environment: The use environment is expected to be in an office environment under typical office conditions in hospitals or medical practices. Operation Principle: The software acts as modality for display of CT or MR imaging data, and for visualization of the image analysis results on a computer system. MeVis Liver Suite does not come into direct contact or indirect contact with patients or other medical devices.
Primary Predicate device: Siemens syngo. CT Liver Analysis (K133643)	syngo.CT Liver Analysis is an image analysis software for CT volume data sets. It analyses the liver and its intrahepatic vessel structures to identify the vascular territories of sub-vessel systems in the liver. These regions can be evaluated by exploring the volume of the liver and its vascular territories. Using syngo.CT Liver Analysis, you can evaluate the liver volume and examine the vessels of the liver. The following evaluation tools are provided: • Computation and manual correction of liver volumes • Computation and manual correction of tumor volumes and extent • Computation and manual correction of liver vessel tree structure • Computation of territories based on vessel branches • Tumor position in relation to vessels (i.e. 3D visualization of liver, tumor and vessels) • Manual definition of separation plane proposals • Computation of volume of liver parts • Combination of information from different CT and MR phase volumes syngo.CT Liver Analysis facilitates reporting by using of appropriate reporting tools, for example, volume statistics and key image creation. You can use syngo.CT Liver Analysis to create a DICOM Structured Report.
Secondary Predicate device: Radiomics App v1.0 (K173420)	Microsoft Radiomics Advanced Image Contouring v1.0 (Radiomics App) is a software-only medical device intended for use by trained radiation oncologists, dosimetrists and physicists to derive optimal organ and tumor contours for input to radiation treatment planning. Supported image modalities are Computed Tomography and Magnetic Resonance. Radiomics App assists in the following scenarios: Load, save and display of medical images and contours for treatment evaluation and treatment planning.

	Creation, transformation, and modification of contours for applications including, but not limited to: transferring contours to radiotherapy treatment planning systems, aiding adaptive therapy, and archiving contours for patient followup. Localization and definition of both solid tumors and healthy anatomical structures. Fusion display of compatible images for treatment planning. Three-dimensional rendering of medical images and the segmented contours. Images reviewed using the Radiomics App software should not be used for primary image interpretations. Radiomics App is not for use with digital mammography.

Table 2 Comparison table for Substantial Equivalence Discussion

Feature/ Item	MeVis Liver Suite (subject device)	Primary Predicate device	Secondary Predicate device
Device Name	**MeVis Liver Suite**	**Siemens syngo. CT Liver Analysis**	**Radiomics App v1.0**
510(k) Number	K232045	K133643	K173420
Indications for Use	See above	See above	See above
Intended Users	The intended users are radiologists and surgeons.	intended for use by physicians	intended for use by trained radiation oncologists, dosimetrists and physicists to derive optimal organ and tumor contours for input to radiation treatment planning.
Patient population	The intended patients for MeVis Liver Suite are oncologic patients or hepatic donor/transplant patients. CT or MR imaging with contrast agents need to be possible for analysis of vascular structures inside the liver. The age group for the intended patient population is 18 or older. In addition, the semi-automatic pre-segmentation tools are restricted to CT scans of potential living liver donors with healthy livers.	Patients requiring analysis of liver and its intrahepatic vessel structures. (No restrictions regarding healthy liver donors, oncologic patients, …)	Oncologic patients Designed to contour/delineate both healthy anatomical structures as well as lesions such as solid tumors.
Intended Part of the Body	Images supported for the intended medical indication include the abdominal body part with the liver and related vascular structures (bile ducts, hepatic artery, hepatic vein, portal vein, inferior vena cava).	liver and its intrahepatic vessel structures	No restrictions.
Product Code	JAK	JAK	LLZ

Software	Standalone software	Image analysis software for syngo.via	Software only medical device
OS	Windows 10 (64-bit)	syngo.via platform	Microsoft Windows
Supported Modalities	DICOM CT and MR	CT and MR	CT and MR
Image import and selection	DICOM images are manually selected and imported into MeVis Liver Suite.	The user has to decide which anatomical structures need to be evaluated and on which CT series the necessary structures have to be segmented.	The user manually loads images into the software.
Segmentation of abdominal organs	• Liver, • Stomach, • Duodenum, • Spleen, • Kidney, • Gallbladder, and • Pancreas Manual segmentation, user-defined manual labelling, and 3D visualization. For segmenting the liver, the user can trigger a **semi-automatic pre-segmentation** that creates contours of the **liver**. The created contours can be manually corrected with interactive contouring tools.	• Liver Automatic segmentation of liver, interactive manual correction of the resulting contour.	• No restrictions Assisted and automatic contouring modes. Creation, transformation, and modification of contours.
Segmentation of liver related vascular structures	Manual segmentation, user-defined manual labelling, and 3D visualization of liver related vascular structures (bile ducts, hepatic artery, hepatic vein, portal vein, inferior vena cava). **Semi-automatic pre-segmentation for liver related vascular structures** is available: the user can click in a user-identified vessel and the software detects the connected vessels. The user can manually correct, add, or delete detected vessels interactively	Segmentation of tubular structures using a semi-automated segmentation of arterial, portal venous and venous vascular bile ducts tree. The segmentation is performed by setting seed point into vessels entering the liver and the system automatically starts to segment the whole intrahepatic vascular object. The user can manually add or delete vessels.	n/a
Segmentation of lesions	Lesions inside and adjacent to the liver Manual segmentation, user-defined manual labelling, and 3D visualization of lesions inside and adjacent to the liver.	Semi-automated segmentation of liver lesions. The user triggers automatic segmentation by drawing a stroke across a lesion at its largest extent. The user can correct the given contour of a lesion.	Tumors Creation, transformation, and modification of contours. Localization and definition of solid tumors.
Users can evaluate the segmented objects by	Abdominal organs (i.e., liver, stomach, duodenum, spleen, kidney, gallbladder, pancreas)	Computation and manual correction of liver volumes.	Segmentation volume

exploring, calculating, and manually correcting the volume of manually segmented objects of interest	Lesions inside and adjacent to the liver (according to their user defined label) Manually defined parts of the liver “Separation Proposals”:” The user can manually define separation planes that part the liver into virtual parts. The user manually labels the parts as either “resection”/”graft”. Manually defined parts of the liver “Vascular territories”: Using the user-defined labelling of vessel branches the software can approximate 3D visualizations of vascular territories within the liver and calculate the appropriate volumes of the different parts	Computation and manual correction of tumor volumes and extent. Manual definition of separation plane proposals and computation of volume of liver parts. Computation of territories based on vessel branches by semi-automated 3D mapping of vascular territories onto liver tissue and computation of volume of liver parts.	
3D visualizations of user-defined (vascular) tumor margins (coloring of area - based on user-defined margin sizes/distances - between the edges of user-defined lesions in relation to the edges of user-defined vascular structures of the liver)	The user can manually enter different margin values, which are used to create color-coded 3D visualizations around user defined lesions.	Tumor position in relation to vessels (i.e. 3D visualization of liver, tumor and vessels). The margin size can be chosen interactively for calculating safety margin around given tumors.	2d distance measurement
Based on user provided values, calculation of liver volume to body weight ratios	The user can enter the weight and height of a patient. Using the user-defined manually created segmentations, MeVis Liver Suite can calculate liver volume to body weight ratios (i.e., estimated weight for remnant or graft, body surface area, graft to recipient body weight ratio, graft to SLV ratio, remnant to body weight ratio).	n/a	n/a
Spatial Registration	Using a manual spatial registration of the images, the segmentations created on different images (i.e. different CT phases and MRI sequences) can be visualized together. The user can manually align the images in pairs on top of each other using manual rigid registration	Manual rigid registration of CT phase volumes - In case more than one CT (or MR) series has been selected, the series have to be manually aligned to each other to match up the liver anatomy, using the manual alignment tool.	Manual rigid registration.

Reporting	Reporting the results of image analysis.	Reporting - All findings generated by the user as well as calculated volumes and 3D images of the structures are summarized in one report.	n/a

9 Performance Data

Non-clinical Tests Discussion:

MeVis Liver Suite is the result of combining functionalities of the predicate devices into a single new device. The validation and verification covered successful testing of the performance and functionality of the subject device with respect to conformance to specifications. For validation, human factors and usability engineering has been applied during development, which included a formative evaluation as well as a summative evaluation with the intended user group. In addition, user acceptance tests were conducted in order to get clinical feedback and to demonstrate that MeVis Liver Suite supports clinical workflows.

The performance of the AI pre-segmentation for the liver and liver related vasculature has been validated in a retrospective multi-center performance study:

Liver: For semi-automatic AI pre-segmentation of the liver, MeVis Liver Suite achieved a mean and median DICE score > 85% with a median 95% Hausdorff (HD) value of <2.0 mm. Subgroup analysis indicates that the AI algorithm generalize well across all subgroups. Compared to the reference device AI-Rad Companion Organs RT (K193562), both the DICE score and the HD value were similar in nature and achieved appropriate quality. As it can be seen in Table 3, the achieved performance of the MeVis Liver Suite liver AI pre-segmentation algorithm and reference device are comparable in DICE and Hausdorff Distance.

Table 3 Performance comparison of liver AI pre-segmentation between MeVis Liver Suite and reference device.

	DICE	95% Hausdorff Distance (HD)
AI-Rad Companion Organs RT (K193562)	Median: 0.85	Median: 2.0 mm
MeVis Liver Suite	Median: 0.98 Mean: 0.98	Median: 1.5 mm

Liver related vasculature: For the semi-automatic AI pre-segmentation of vascular structures HV, PV and HA, bench tests that compare the output of the AI pre-segmentation algorithms with ground truth annotated by qualified experts show that the algorithms performed as expected.
For a representative clinical multi-center dataset, the AI pre-segmentation results were assessed by 3 board certified surgeons/radiologists using a 5-point Likert scale. The qualitative scoring demonstrates that >80% of all expert scores rated the algorithm results as sufficiently accurate in the context of the clinical use.

Volume calculation of segmentations by MeVis Liver Suite are successfully verified and validated via simulated phantom and clinical test data:

- The accuracy of volume is validated by comparing the measured volume of lesions in digital simulated phantom data with a reference value. The pass criteria for accuracy of volume calculation is fulfilled.

- Clinical test data was used to validate the precision of volume calculation in terms of repeatability. The pass criteria for precision of volume calculation based on a representative test data set is fulfilled

The results of performance, functional, and validation testing demonstrate that the subject device MeVis Liver Suite meets the specification and intended use, and is substantially equivalent to those of the listed predicate devices.

Clinical Tests Discussion:

N/A - No clinical testing has been conducted to demonstrate substantial equivalence.

10 Conclusion

MeVis Medical Solutions has determined that its device, MeVis Liver Suite, is substantially equivalent to the identified predicate devices listed above. A comparison with the legally marketed predicate devices indicates that it is substantially equivalent to these devices, and that it does not raise any new safety or efficacy concerns. Non-clinical tests demonstrate that the device is substantially equivalent to the predicate devices.