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

February 23, 2021

Re: K201501
Trade/Device Name: Veolity
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: OEB, LLZ
Dated: January 20, 2021
Received: January 26, 2021

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201501

Device Name
Veolity

Indications for Use *(Describe)*
Veolity is intended to:

- display a composite view of 2D cross-sections, and 3D volumes of chest CT images,
- allow comparison between new and previous acquisitions as well as abnormal thoracic regions of interest, such as pulmonary nodules,
- provide Computer-Aided Detection ("CAD") findings, which assist radiologists in the detection of solid pulmonary nodules between 4-30 mm in size in CT images with or without intravenous contrast. CAD is intended to be used as an adjunct, alerting the radiologist – after his or her initial reading of the scan – to regions of interest that may have been initially overlooked.

The system can be used with any combination of these features. Enabling/disabling is handled via licensing or configuration options.

Intended Patient Population:
Veolity is an imaging software including computer assisted reading tools for reviewing CT examinations of the chest on an asymptomatic population.

Intended Conditions of Use:
As a software-only product, Veolity does not come into direct contact or indirect contact with patients, and it is neither a sterile device nor an in vitro diagnostic device. Additionally, the environmental and location requirements as defined for the hardware running Veolity apply. The software does not alter these requirements.

Intended User Profile:
Veolity is intended to be used by medical professionals (e.g., radiologists) with adequate training.

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

K201501

001_005: 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: 06/03/2020

Date Adjusted: 02/22/2021

Contact Person: Rolf Rzodeczko
Manager Regulatory Affairs

Telephone: +49 (0)421 22495-120

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2 Device

Device Trade Name: Veolity

Common Name: Medical Imaging Processing Software, Medical Imaging Workstation

Regulation: CFR 21 892.2050

Classification Name: Lung Computed Tomography System, Computer-aided Detection, Picture archiving and communications system

Product Code: OEB, LLZ

Class: Class II

Panel: Radiology

3 Predicate Devices

510(k) Number	Predicate Device	Product Code
K043617	ImageChecker CT CAD Software System	OEB
K023003	ImageChecker-CT Workstation	LLZ
K040028	Comprehensive Chest Analysis Tools (C-CAT)	LLZ

4 Reference Device

510(k) Number	Reference Device	Product Code
K162484	Lung Nodule Assessment and Comparison Option (LNA)	LLZ, JAK

5 Device Description

Veolity is a medical imaging software platform that allows processing, review, and analysis of multi-dimensional digital images.
The system integrates within typical clinical workflow patterns through receiving and transferring medical images over a computer network. The software can be loaded on a standard off-the-shelf personal computer (PC). It can operate as a stand-alone workstation or in a distributed server-client configuration across a computer network.

Veolity is intended to support the radiologist in the review and analysis of chest CT data. Automated image registration facilitates the synchronous display and navigation of current and previous CT images for follow-up comparison

The software enables the user to determine quantitative and characterizing information about nodules in the lung in a single study, or over the time course of several thoracic studies. Veolity automatically performs the measurements for segmented nodules, allowing lung nodules and measurements to be displayed. Afterwards nodule segmentation contour lines can be edited by the user manually with automatic recalculation of geometric measurements post-editing. Further, the application provides a range of interactive tools specifically designed for segmentation and volumetric analysis of findings in order to determine growth patterns and compose comparative reviews.
Veolity requires the user to identify a nodule and to determine the type of nodule in order to use the appropriate characterization tools. Additionally, the software provides an optional/licensable CAD package that analyzes the CT images to identify findings with features suggestive of solid pulmonary nodules between 4-30 mm in size. The CAD is not intended as a detection aid for either part-solid or non-solid lung nodules. The CAD is intended to be used as an adjunct, alerting the radiologist – after his or her initial reading of the scan – to regions of interest that may have been initially overlooked.

The system can be used with any combination of these features. Enabling/disabling is handled via licensing or configuration options.

From workflow perspective, incoming chest CT data is processed and prepared by the CAD server software. Ready to read data is transferred to the viewing client software. Radiologists can read and analyze the data by using different tools and compare current and prior images. Finally, findings can be reported and forwarded to long-term archives.

Veolity may be utilized in both diagnostic and screening evaluations supporting Low Dose CT Lung Cancer Screening[1].

Key Features

1. Synchronized side-by-side viewing between studies from different time points (temporal comparative review 2D/3D)
2. Automatic lung segmentation
3. Automatic pulmonary nodule segmentation with manual editing tools
4. Propagation of previously segmented nodules from prior studies for comparison
5. Automatic calculation of the following measurements for each segmented nodule:
    a. Quantification of nodule measurements:
        i. Long Axis (longest diameter on an axial slice (mm))
        ii. Short Axis (longest diameter perpendicular to the long axis on the same slice (mm))
        iii. Average \ Equivalent Diameter (mm)
        iv. Volume (mm3)
        v. Density (HU)
        vi. Mass (mg)

        Manual edit of the nodule segmentation contour lines with automatic recalculation of geometric measurements post-editing
    b. Specification of the following nodule characteristics:
        i. Nodule type (solid, part-solid, non-solid, calcified, perifissural, endobronchial)
        ii. Lobe/segment location
        iii. Nodule spiculation
    c. Temporal comparison of the following matching nodule measurements between each follow-up scan and the previous scan:
        i. Mass and volume doubling time in days
        ii. Volume change in percent (%)
        iii. Absolute change of nodule measurements
6. Reporting results including patient related information and nodule measurements
7. Pre-fill function for reporting based on ACR Lung-RADS guidelines
8. Nodule Risk Calculator tool based on patient and nodule characteristics for estimation of the probability that lung nodules detected on baseline screening low-dose CT scans are malignant, based on McWilliams, Annette, et al. "Probability of cancer in pulmonary nodules detected on first screening CT." New England Journal of Medicine 369.10 (2013): 910-919.

[1] The screening must be performed within the established inclusion criteria of programs/ protocols that have been approved and published by either a governmental body or professional medical society.
Please refer to clinical literature that includes the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

9. Computer-Aided Detection (CAD) of solid pulmonary nodules between 4-30 mm in size (only to be used as an adjunct, alerting the radiologist – after his or her initial reading of the scan – that may have been initially overlooked)

Additional Information for Risk Calculator:
The malignancy risk calculator feature in Veolity is based on the full model with spiculation developed by Brock University as described in McWilliams, et al (2013). This model allows estimating the probability that lung nodules detected on baseline screening low-dose CT scans are malignant.
The model's performance was validated using two large population-based prospective studies: the Pan-Canadian Early Detection of Lung Cancer Study (PanCan) and the chemoprevention trials at the British Columbia Cancer Agency (BCCA), sponsored by the U.S. National Cancer Institute.

Further details can be found in *McWilliams, A., Tammemagi, M.C., Mayo, J.R., Roberts, H., Liu, G., Soghrati, K., Yasufuku, K., Martel, S., Laberge, F., Gingras, M. and Atkar-Khattra, S., (2013). Probability of cancer in pulmonary nodules detected on first screening CT. New England Journal of Medicine, 369(10), pp.910-919*

6 Indications for Use

Veolity is intended to

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- allow comparison between new and previous acquisitions as well as abnormal thoracic regions of interest, such as pulmonary nodules
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Intended User Profile:
Veolity is intended to be used by medical professionals (e.g. radiologists) with adequate training.

7 Technological Characteristics Comparison

Veolity is a modified version of the previously cleared primary predicate device ImageChecker CT CAD Software System (K043617). As the new device Veolity integrates the functionality of the predicate devices and the reference device to a single device, the new device and the entirety of the predicate and reference devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. The integrated usage was addressed and cleared for each predicate/reference device. The new device does not raise any new potential safety risks and is equivalent in performance to the existing legally marketed devices.

8 Performance Data

Non-clinical Tests Discussion:

As Veolity is the result of combining the predicate and reference devices into a single new device, the intended use changed and summarizes the intended use of all predicate devices. However, the individual functionalities of the predicate devices are used technically unchanged.

The complete functionality of subject device is covered through the Validation and Verification Plan and has been tested with respect to conformance to specifications.

In addition, the subject device's CAD system performance provides equal results in terms of sensitivity and false positive rates compared to the primary predicate device. This performance assessment is based on the panel review results that were subject in the initial submission of the predicate device.

Furthermore, the performance has been re-evaluated with a multi-center dataset with modern and multivendor CT data in terms of sensitivity and false positive rate per case. A comparable study design to the clinical study of the primary predicate device was used.
The study demonstrated that the performance to detect solid actionable pulmonary nodules on modern data with subject device is equivalent to the primary predicate device.

In general, the performance of subject device is maintained using test data enriched with modern CT data.

Clinical Tests Discussion:

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

9 Conclusion

MeVis Medical Solutions has determined that its device, Veolity, is substantially equivalent to the entirety of the predicate and reference devices listed above. Resulting from the new product setup of combining the three formerly cleared separate medical devices to one medical device, the intended use changed. However, the main functionalities of the former devices remain unchanged. A comparison with the legally marketed predicate and reference devices indicates that it is substantially equivalent to the entirety of these devices, has the same (combined) intended use, principles of operation and technological characteristics and that it does not raise any new safety or efficacy concerns. Non-clinical tests demonstrate that the device is safe, effective, and is substantially equivalent to the entirety of the predicate and reference devices.