June 21, 2024

JLK Inc.
% John Smith
Partner
Hogan Lovells US LLP
555 13th Street, NW
Washington, District of Columbia 20004

Re: K233196
Trade/Device Name: Medihub Prostate
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: May 10, 2024
Received: May 10, 2024

Dear John Smith:

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,

Daniel M. Krainak, PhD
Assistant Director
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
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)*
K233196

Device Name
MEDIHUB PROSTATE

Indications for Use *(Describe)*
MEDIHUB PROSTATE is an image processing software package that performs outlining, processing, viewing, and editing of prostate MR images. The software can support study review and analysis of prostate MR data with computed modules. The analysis result can be presented in various formats, including images overlaid onto source MR images and a structured report.
MEDIHUB PROSTATE semi-automatically outlines the prostate based on MR images by contour, and it requires the user to edit with image manipulating tools and confirm the final result. The package provides additional functionalities including registered multiparametric-MRI viewing and combining MR sequences into a single image to support visualization. Edited PI-RADS report and semi annotated prostate region can be viewed in each single image in the final report.
MEDIHUB PROSTATE is intended to be used by trained radiologists and urologists. Patient management decisions should not be made solely based on the analysis performed by MEDIHUB PROSTATE.

Limitations:
* MEDIHUB PROSTATE has been validated for use with Siemens 3T Vida and Skyra MRI machines.
* MEDIHUB PROSTATE is also designed for use with the Siemens 3T T2 MRI series, supporting slice thicknesses ranging from 3.5 mm to 5 mm.
* MEDIHUB PROSTATE has been tested on patients aged 55 years and above.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

JLK's MEDIHUB PROSTATE

K233196

I. SUBMITTER

JLK Inc.
5, Teheran-ro 33-gil, Gangnam-gu,
Seoul, Republic of Korea
Phone: (+82) 02 6925 6189
FAX: (+82) 0505 300 4051
Contact person / E-mail: Dongmin Kim / dmkim@jlkgroup.com
Date Prepared: June 14, 2024

II. DEVICE

Name of Device: MEDIHUB PROSTATE
Common or Usual Name: MEDIHUB PROSTATE
Classification Name: Medical image management and processing system
Regulatory Class: II
Product Code: QIH
Classification regulation: 21 CFR 892.2050

III. PREDICATE DEVICE

Device: Quantib Prostate
Manufacturer: Quantib B.V.
510(k) No: K202501
Product Code: LLZ
Regulatory Class: II

IV. DEVICE DESCRIPTION

MEDIHUB PROSTATE is an image processing software package for multi-parametric prostate MR image analysis. The analysis may assist trained radiologists and urologists in clinical interpretation of prostate MR studies. It can be accessed through a web browser, and provides the following main features:

- A semi-automatic processing module that outlines the prostate region and performs multi-parametric MRI image registration.
- A user-interaction module in which the user can edit and approve the computed prostate outline and determine PSA density using serum PSA level.
- A user-interaction module in which the user can view multi-parametric MRI images, and outline and analyze ROIs. This extension will also apply a mathematical operation on the input images to combine information from another MRI sequences into a single combination image.

- A semi-automatic processing module that collects all results for exporting and transferring back to the user.

All measurements are manual except for the prostate volume, which is semi-automatic and requires user review. The method for measuring prostate volume is straightforward and unaffected by patient demographics. Users have the option to outline the prostate either completely manually or with semi-automatic assistance. This device is not intended to be used for fully automatic prostate delineation. It does not involve any segmentation functions by itself. The AI functionality is limited to assessing the total prostate volume, without segmenting lesions.

In semi-automatic mode, our device employs an AI-based algorithm to initially outline the prostate volume, and then it requires the user to edit, review and approve. Additionally, the device calculates the total prostate volume. However, users are responsible for performing all other image annotations and measurements manually. This implies that the final decision should be confirmed by the user, and the user should not rely solely on the device's analysis.

Additional annotations and measurements: all calculated manually

- PI-RADS
- Location of seminal vesicles
- Prostate zones
- DWI and DCE graphs

V. INDICATIONS FOR USE

MEDIHUB PROSTATE is an image processing software package that performs outlining, processing, viewing, and editing of prostate MR images. The software can support study review and analysis of prostate MR data with computed modules. The analysis result can be presented in various formats, including images overlaid onto source MR images and a structured report.

MEDIHUB PROSTATE semi-automatically outlines the prostate based on MR images by contour, and it requires the user to edit with image manipulating tools and confirm the final result. The package provides additional functionalities including registered multiparametric-MRI viewing and combining MR sequences into a single image to support visualization. Edited PI-RADS report and semi annotated prostate region can be viewed in each single image in the final report.

MEDIHUB PROSTATE is intended to be used by trained radiologists and urologists. Patient management decisions should not be made solely based on the analysis performed by MEDIHUB PROSTATE.

Limitations:

- MEDIHUB PROSTATE has been validated for use with Siemens 3T Vida and Skyra MRI machines.
- MEDIHUB PROSTATE is also designed for use with the Siemens 3T T2 MRI series, supporting slice thicknesses ranging from 3.5 mm to 5 mm.
- MEDIHUB PROSTATE has been tested on patients aged 55 years and above.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

MEDIHUB PROSTATE shares similar indications for use, technological characteristics, and principles of operation with its predicate device. At a high level, both the subject device and predicate device are based on the same technological elements as follows:

Substantial Equivalence Chart

Item	MEDIHUB PROSTATE	Quantib Prostate (K202501)	Substantial Equivalence
Regulatory Data			
Regulatory Class	Class II	Class II	**Equivalent**
Classification Name	Medical image management and processing system	Picture archiving and communications system	**Equivalent**[1]
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	**Equivalent**
Product Code	QIH	LLZ	**Equivalent**
Use			
Target users	Trained medical professionals	Trained medical professionals	**Equivalent**
Anatomical site	Prostate	Prostate	**Equivalent**
Where used	Hospital	Hospital	**Equivalent**
Workflow Considerations	• User can approve or reject results • User can inspect and edit prostate segmentation • User can enter PSA value and compute PSA density • User can create and update regions of interest (ROIs) • User can add and update annotations (text) to analysis • User can manually set a PI-RADS score using a PI-RADS interactive worksheet	• User can approve or reject results • User can inspect and edit prostate segmentation • User can enter PSA value and compute PSA density • User can create and update regions of interest (ROIs) • User can add and update annotations (text) to analysis • User can manually set a PI-RADS score using a PI-RADS interactive worksheet	**Equivalent**
Technical characteristics			

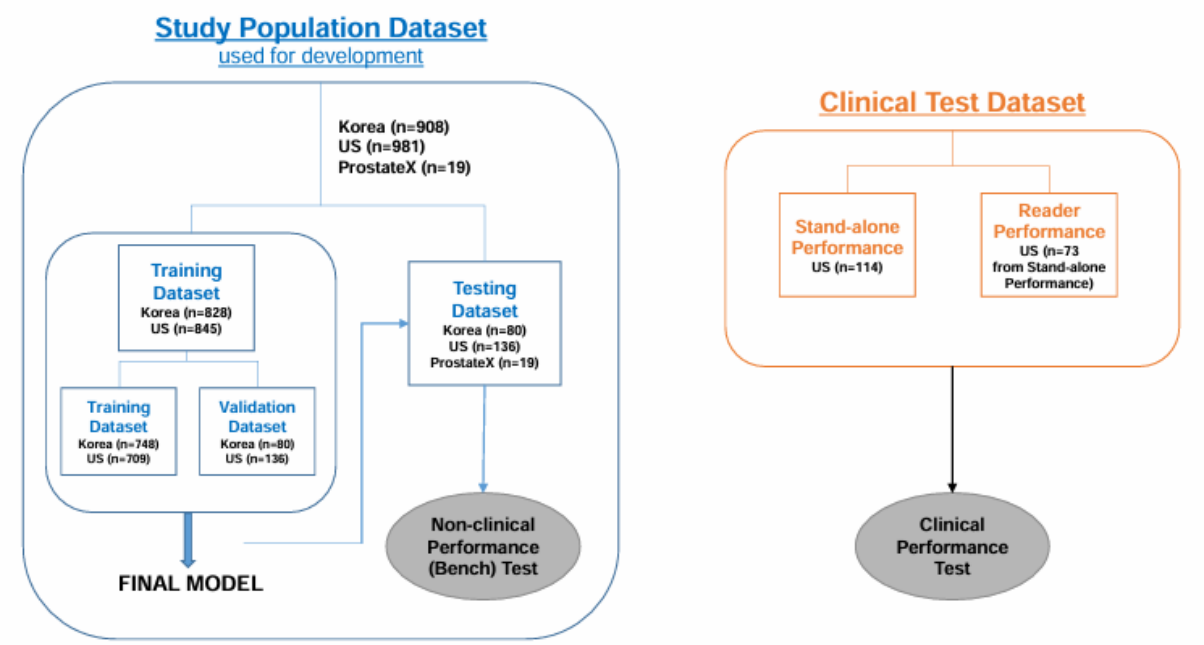
[1] The name of the generic devices regulated under 21 C.F.R. 892.2050 has been changed from Picture archiving and communications system to Medical image management and processing system as part of FDA's implementation of the 21st Century Cures Act.

Item	MEDIHUB PROSTATE	Quantib Prostate (K202501)	Substantial Equivalence
Design	• Semi-automatic prostate segmentation • Multi parametric image review • Biparametric combination image viewer • Basic image manipulation tools, Thresholding tool • User interface to create/update user generated ROIs	• Semi-automatic prostate segmentation • Multi parametric image review • Biparametric combination image viewer • Basic image manipulation tools, Thresholding tool • User interface to create/update user generated ROIs	**Equivalent**
Non-clinical performance	• Bench testing performed to test the functionality of the system • This included characterization of the standalone performance of the prostate segmentation algorithm.	• Bench testing performed to test the functionality of the system • This included characterization of the standalone performance of the prostate segmentation algorithm.	**Equivalent**
Clinical performance	• Prostate segmentation algorithm was tested in a clinical use context • i.e. as a semiautomatic algorithm after correction by trained clinicians.	• Prostate segmentation algorithm was tested in a clinical use context • i.e. as a semiautomatic algorithm after correction by trained clinicians.	**Equivalent**
Standards met	• IS0 14971 – Medical devices –Application of risk management to medical devices • IEC 62304 – Medical device software – Software life cycle processes • IEC 62366 – Medical devices – Application of usability engineering to medical devices	• IS0 14971 – Medical devices –Application of risk management to medical devices • IEC 62304 – Medical device software – Software life cycle processes • IEC 62366 – Medical devices – Application of usability engineering to medical devices	**Equivalent**
SW verification and validation	• Tested in accordance with verification and validation processes and planning • The testing results support that all the system requirements have met their acceptance criteria and are adequate for its intended use	• Tested in accordance with verification and validation processes and planning • The testing results support that all the system requirements have met their acceptance criteria and are adequate for its intended use	**Equivalent**

Item	MEDIHUB PROSTATE	Quantib Prostate (K202501)	Substantial Equivalence
Compatibility with the environment and other devices	DICOM compatible	DICOM compatible	**Equivalent**
Reported measures	Prostate gland Volume, PSA density, ROIs within the prostate, with for each ROI: • Volume • Average ADC value • PI-RADS score • Location	Prostate gland volume, PSA density, ROIs within the prostate, with for each ROI: • Volume • Average ADC value • PI-RADS score • Location	**Equivalent**
Required input	DICOM compatible data, type of MRI scans: T2-weighted, DWI, ADC, DCE	DICOM compatible data, type of MRI scans: T2-weighted, DWI, ADC, DCE	**Equivalent**

VII. PERFORMANCE DATA

Data Description



Study Population Dataset: The Study Population Dataset is the same as algorithm development dataset. The dataset consists of three sets, Korea, US (the University of Missouri Health Care), and ProstateX (open dataset). The dataset is split into Training/Validation/Testing dataset. In Phase I, a Stand-alone Performance test was conducted, and in Phase II, a Reader Performance test was conducted. In the Study Population Dataset, the Training/Validation datasets and the Testing dataset were stratified at a ratio of 9:1. Additionally, within the Training/Validation split, the Training dataset and the Validation dataset were further stratified at a ratio of 9:1. The data used

to demonstrate performance of the device included Siemens 3T Vida and Skyra systems with slice thickness ranging from 3.5 to 5 mm.

Algorithm Performance Testing

A performance check test was conducted on the prostate region segmentation algorithm of MEDIHUB PROSTATE. The performance was obtained by comparing the ground truth produced by three expert radiologists and the results of the prostate region segmentation algorithm. The performance was measured by the mean value of Dice coefficient and Hausdorff Distance of the test group. The results were obtained and calculated by computer coding, and the score for each case was recorded. Utilizing the test datasets of Korea patients, US patients, and ProstateX (open dataset), the performance of the prostate region segmentation function was evaluated. Calculating the Dice coefficient between ground-truth and algorithm prediction yields the performance. The pass/fail criterion for each dataset is whether the mean Dice coefficient exceeds 0.894, which is determined by analyzing the results of the most recent state-of-the-art prostate region segmentation algorithm published in the past 5 years; this value is the average of performance in articles whose performance is greater than the average of the entire references. The value is calculated as the lower limit of 99%, confidence interval based on the performances of whole reference. As a consequence, the criteria were met by all three test datasets.

Clinical Testing (Stand-alone Performance)

The purpose of this study is to verify the stand-alone performance of the prostate region segmentation algorithm. MEDIHUB PROSTATE was developed by applying a deep learning technique on T2 prostate MRI. The clinical test investigator collected data that met the inclusion criteria and no subjects met the exclusion criteria. Based on a total of 114 T2 MR images (University of Missouri Hospital) the final validity evaluation was performed on prostate region segmentation ground truth produced by three expert radiologists. In this clinical test, it was confirmed that mean Dice coefficient was higher than the predefined primary efficacy evaluation criterion. The clinical testing results demonstrated that the overall Dice coefficient and Hausdorff distance were 0.928 and 2.171, respectively, with the 95% confidence intervals for these measurements being [0.925, 0.931] for the Dice coefficient and [1.097, 3.245] for the Hausdorff distance.

Ground Truthing Process

The ground truthing was conducted by expert-level radiologists. They independently annotated the prostate images, and these annotations were then consolidated into a definitive ground truth through a majority rule approach. The rationale for employing consensus among three radiologists, resolved through discussion and mutual agreement in cases of ties, ensures a reliable and unbiased representation of the prostate, crucial for the accurate clinical performance evaluation of our device.

Clinical Testing Dataset Distribution

Demographic information on subjects (N=114)

Gender, n(%)	Male, 114 (100%)	
Age	Mean ± SD	66.38 ± 5.33
	Median (Min, Max)	66 (57, 78)

Age group, n (%)	55~59	14 (12.3%)
	60~69	63 (55.3%)
	70~79	37 (32.5%)
Races	White	106 (92.9%)
	African American	7 (6.1%)
	Asian	1 (0.9%)

※ As indicated in a paper by Mavropoulos (2007)[2], there is no significant association between race and prostate size. Given that race or ethnicity does not impact measuring prostate area or volume.

95% confidence interval of the dice coefficient and Hausdorff distance calculated by comparing ground truth and the result of algorithms by race

Race	Dice Coefficient	Hausdorff Distance
White	0.929 *[0.925, 0.933]	2.173 *[2.066, 2.280]
African American	0.925 *[0.902, 0.949]	2.085 *[1.711, 2.459]
Asian	0.917 *[nan, nan]	2.929 *[nan, nan]

* 95% Confidence Interval

95% confidence interval of the dice coefficient and Hausdorff distance calculated by comparing ground truth and the result of algorithms by age

Age	Dice Coefficient	Hausdorff Distance
< 60	0.938 *[0.925, 0.950]	1.871 *[1.638, 2.103]
≥ 60	0.927 *[0.923, 0.931]	2.224 *[2.114, 2.335]

* 95% Confidence Interval

Clinical Testing (Reader Performance)

The purpose of this study is to compare the reader performance with and without the prostate region segmentation algorithm of MEDIHUB PROSTATE. Dice coefficients of the investigators' performances are calculated by comparing the ground truth of the prostate region segmentation with each investigator's segmentation results. The results were better when all three expert radiologists were with aid of the prostate region segmentation algorithm of MEDIHUB PROSTATE. And regardless of by race and age, the results were better in all cases with aid of the prostate region segmentation algorithm of MEDIHUB PROSTATE. The improvements in the Dice coefficient

[2] Mavropoulos, J. C., Partin, A. W., Amling, C. L., Terris, M. K., Kane, C. J., Aronson, W. J., ... & Freedland, S. J. (2007). Do racial differences in prostate size explain higher serum prostate-specific antigen concentrations among black men?. Urology, 69(6), 1138-1142.

for prostate outlining performance for the three radiologists when using the prostate region segmentation algorithm of MEDIHUB-PROSTATE were 0.156, 0.011, and 0.008, respectively.

Properties of Performance Testing Cases

Properties	Value
Sites	University of Missouri Health Care
Field Strengths	3*T*
MR Scanner Manufacturer	SIEMENS, Siemens HealthCare GmbH
Thickness	3.5*mm, 5mm*
Purpose of AI	Prostate region semi auto-segmentation

Safety Implications

MEDIHUB PROSTATE is intended to support trained radiologists and urologists. The software does not make diagnoses; it provides quantification results that must be interpreted by a trained radiologists and urologists before using the device. MEDIHUB PROSTATE is both software applications running on off-the-shelve hardware. In conclusion, MEDIHUB PROSTATE does not introduce any new safety issues compared to the predicate device Quantib Prostate.

VIII. DISCUSSION & CONCLUSIONS

Discussion

MEDIHUB PROSTATE employs a deep learning model to semi-automatically outline the prostate region. Its performance is evaluated using the Dice coefficient against ground-truth data from Korea patients, US patients, and an open dataset (ProstateX). The pass/fail criterion, set at a mean Dice coefficient of 0.894, is determined by recent state-of-the-art algorithms. Results show that all three test datasets meet this criterion, with Dice coefficients surpassing 0.866 in every case, demonstrating substantial equivalence.

Conclusions

MEDIHUB PROSTATE is semi-automatic image processing software. Clinical test results indicate its safety as it does not affect patients according to the software's results. By utilizing the semi-automatic drawing function of the software, it demonstrates efficiency in improving the accuracy of user's prostate region segmentation, making it as safe and effective as the Quantib Prostate. MEDIHUB PROSTATE has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. In addition, the minor technological differences between the MEDIHUB PROSTATE and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the MEDIHUB PROSTATE is as safe and effective as the Quantib Prostate. Thus, the MEDIHUB PROSTATE is substantially equivalent.