Quantib BV
℅ Arnault Massink
Quality & Regulatory Manager
Westblaak 106
3012 KM Rotterdam, Zuid-Holland
NETHERLANDS

May 13, 2022

Re: K221106
Trade/Device Name: Quantib Prostate (version 2.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: April 4, 2022
Received: April 15, 2022

Dear Arnault Massink:

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.
Division Director
DHT8B: 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)*
K221106

Device Name
Quantib Prostate (version 2.0)

Indications for Use *(Describe)*

Quantib Prostate is image post-processing software that provides the user with processing, visualization, and editing of prostate MRI images. The software facilitates the analysis and study review of MR data sets and provides additional mathematical and/or statistical analysis. The resulting analysis can be displayed in a variety of formats, including images overlaid onto source MRI images.

Quantib Prostate functionality includes registered multiparametric-MRI viewing, with the option to view images combined into a single image to support visualization. The software can be used for semi-automatic segmentation of anatomical structures and provides volume computations, together with tools for manual editing. PI-RADS scoring is possible using a structured workflow.

Quantib Prostate is intended to be used by trained medical professionals and provides information that, in a clinical setting, may assist in the interpretation of prostate MR studies. Diagnosis should not be made solely based on the analysis performed using Quantib Prostate.

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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Quantib Prostate 2.0 Special 510(k) Summary

1 SUBMITTER

Quantib B.V.
Westblaak 106
3012 KM Rotterdam
Phone: (+31) 108 41 17 49
Contact Person: Floor van Leeuwen
Date Prepared: April 4th, 2022

2 DEVICE

Name of Device: Quantib Prostate - version 2.0
Common or Usual Name: Quantib Prostate
Classification Name: System, image processing, radiology (892.2050)
Regulatory Class: II
Product Code: Medical image management and processing system (former Picture archiving and communication system) - LLZ

3 PREDICATE DEVICE

Device: Quantib Prostate – version 1.0
Manufacturer: Quantib B.V.
510(k) Reg. No: K202501
This predicate has not been subject to a design-related recall.
Classification Name: System, image processing, radiology (892.2050)
Regulatory Class: II
Product Code: Medical image management and processing system (former Picture archiving and communication system) - LLZ

4 DEVICE DESCRIPTION

Quantib Prostate is an extension to the Quantib AI Node software platform and enables analysis of prostate MRI scans. Quantib Prostate makes use of Quantib AI Node functionality, and includes the following specific Quantib Prostate modules:

- An automatic processing module that performs prostate and prostate sub-region segmentation and multi-parametric MRI image registration and computation of a biparametric combination image.
- A user-interaction module in which the user can edit and approve the computed prostate segmentation and determine PSA density.
- A user-interaction module in which the user can view multi-parametric MRI images, segment and analyze potential lesions and set and view PI-RADS properties. This module also shows the prostatic sub-region segmentation and biparametric combination image overlay.
- An automatic processing module that collects all results, and creates the report and DICOM output so that they can be exported back to the user.

5 INDICATIONS FOR USE

Quantib Prostate – version 1.0 and version 2.0
Quantib Prostate is image post-processing software that provides the user with processing, visualization, and editing of prostate MRI images. The software facilitates the analysis and study review of MR data sets and provides additional mathematical and/or statistical analysis. The resulting analysis can be displayed in a variety of formats, including images overlaid onto source MRI images.

Quantib Prostate functionality includes registered multiparametric-MRI viewing, with the option to view images combined into a single image to support visualization. The software can be used for semi-automatic segmentation of anatomical structures and provides volume computations, together with tools for manual editing. PI-RADS scoring is possible using a structured workflow.

Quantib Prostate is intended to be used by trained medical professionals and provides information that, in a clinical setting, may assist in the interpretation of prostate MR studies. Diagnosis should not be made solely based on the analysis performed using Quantib Prostate.

Indications for use comparison

The intended use of the device is **equivalent** to the intended use of the previously cleared predicate device [K202501]

6 DEVICE MODIFICATIONS

Quantib Prostate 2.0 is the first update of Quantib Prostate 1.0 that includes a substantial change. The substantial changes are the following:

1. *Division of prostate segmentation into prostatic sub-regions*
   The semi-automatic prostate segmentation is extended with an algorithm to divide the prostate segmentation into sub-regions (central gland, peripheral zone, and urethra), without impacting the original prostate segmentation. The segmentations are displayed in the mpMRI analysis user interaction step and can be exported as a secondary capture series that also includes the ROI segmentations. Internal boundaries of sub-regions cannot be edited, but user edits of the outer prostate segmentation are reflected in the sub-region outer boundaries. Individual volumes of sub-regions are not provided.

2. *Initialization of ROI location on PI-RADS sector map*
   For an annotated ROI the location on the PI-RADS sector map is now initialized with a cross, based on the sub-region segmentation input when the PI-RADS scoring window is opened. Inspecting, editing and confirming the location should be done manually.

7 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The following technological characteristics are the same for Quantib Prostate 2.0 and its predicate device Quantib Prostate 1.0:

- Indications for use
- Target users, anatomical site, and use environment
- Human factors
- Reported measures
- Design control activities and recognized standards
- Required input, reported measures
- Deployment and compatibility with environment and other devices

The following technological characteristics are different:

- *Software Design:* addition of ROI localization initiation on PI-RADS sector map.
- *Algorithm design and performance:* prostate sub-region segmentation added as segmentation output.
- *Output formats:* additionally presented in a PDF report, DICOM RT structure set and DICOM segmentation storage.

7.1 QUALITY AND SAFETY

Quantib Prostate 2.0 is designed in compliance with the following process standards:

- ISO 14971 – Medical devices - Application of risk management to medical devices
- IEC 62304 – Medical device software – Software life cycle processes
- IEC 62366-1 – Medical devices – part 1 - Application of usability engineering to medical devices

The following quality assurance measures were applied to Quantib Prostate 2.0 development:

- Risk and hazard analysis
- Design and code reviews
- Software verification & validation activities
- Performance testing
- Usability engineering
- Cybersecurity and vulnerability analysis

7.2 PERFORMANCE DATA

The prostate segmentation algorithm and performance are unchanged. For the sub-region segmentation and ROI localization initiation the following performance tests are added:

Non-clinical performance testing:

Bench testing of the software was done to show that the system is suitable for its intended use and to evaluate the stand-alone performance of the sub-region segmentation algorithm. This was done by comparing the automatic sub-region segmentation to a ground truth and calculating the Dice overlap and Mean Surface Distance. To place the agreement between the automatic method and the manual segmentation into context, the results are compared with the inter-observer measurements using statistical tests. Bench testing did not reveal any issues with the system, demonstrating that the modified device is as safe and effective as the predicate device.

Clinical performance:

The clinical performance test of the sub-region prostate segmentation and the ROI localization initiation as seen by the user in a clinical context is conducted in a qualitative manner. Radiologists were asked to score the sub-region segmentations and ROI initial localizations using a 5-point Likert scale. It is concluded that sub-regions and ROI localizations are judged to be of high quality.

8 CONCLUSIONS

By virtue of its intended use and physical and technological characteristics, Quantib Prostate 2.0 is substantially equivalent to a device that has been approved for marketing in the United States. The performance data show that Quantib Prostate 2.0 is as safe and effective as the predicate device.