April 17, 2023

Quantib BV
% Floor van Leeuwen
Quality & Regulatory Director
Westblaak 130
Rotterdam, Zuid-Holland 3012 KM
NETHERLANDS

Re: K230772
Trade/Device Name: Quantib Prostate
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: March 20, 2023
Received: March 21, 2023

Dear Floor van Leeuwen:

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,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
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)*
K230772

Device Name
Quantib Prostate

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.

K230772

Quantib Prostate Special 510(k) Summary

1 SUBMITTER

Quantib B.V.
Westblaak 130
3012 KM Rotterdam
Phone: (+31) 108 41 17 49
Contact Person: Floor van Leeuwen
Date Prepared: March 20th, 2023

2 DEVICE

Name of Device:	Quantib Prostate – version 3.0
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 2.0
Manufacturer:	Quantib B.V.
510(k) Reg. No:	K221106 - 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 (QPR) is an extension to the Quantib AI Node (QBX) software platform that enables analysis of prostate MRI scans. QPR makes use of QBX functionality, and includes 3 specific QPR modules.

The three specific modules of QPR are as follows:

- An automatic processing module that performs input checks, prostate (sub-region) segmentation, multi-parametric MRI (mpMRI) image registration, computation of a biparametric combination image, and optionally crops the images around the prostate.
- A two-step user-interaction module in which the user can:
    - edit the computed prostate segmentation (QBX functionality) and determine PSA density (QPR-specific functionality).
    - view multi-parametric MRI images (QBX functionality), and segment (QBX functionality) and analyze potential lesions (QPR-specific functionality). This extension also shows the prostatic sub-region segmentation and biparametric combination image overlay. (QPR-specific functionality).
- 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

5.1 INDICATIONS FOR USE – QUANTIB PROSTATE VERSION 3.0 AND 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.

5.2 INDICATIONS FOR USE COMPARISON

The intended use of the device is equivalent to the intended use of the previously cleared predicate device [K221106]

6 DEVICE MODIFICATIONS

Quantib Prostate 3.0 is an update of Quantib Prostate 2.0 (the predicate device) that includes a substantial change. The substantial difference is the following:

1. *Improved prostate and sub-region segmentation algorithm*
   The prostate and sub-region segmentation algorithms have been improved by updating the methodology and training it on over 400 scans. In addition, the two algorithms have been combined into one algorithm.

7 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The following technological characteristics are the same for Quantib Prostate 3.0 and its predicate device Quantib Prostate 2.0:

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

The following technological characteristics are different:

- *Human factors*
  1) The user can now switch between user interaction steps when editing and
  2) the ROI drawing on the PI-RADS sketch is now initialized representing the ROI shape and size. This can be edited by the user.
- *Algorithm Design and performance*
  The algorithms for prostate segmentation and prostate subregion segmentation are combined into a single algorithm. This algorithm has been retrained and re-validated. The performance measures of prostate and subregion segmentation are updated correspondingly.
- *Output files and formats*
  3D segmentations of prostate including ROIs are generated and exported as secondary captures. Images of the 3D segmentations are added to the PDF report.

7.1 QUALITY AND SAFETY

Quantib Prostate 3.0 was designed in compliance with the following US recognized consensus standards:

- ISO 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

The following quality assurance measures were applied to Quantib Prostate 3.0 development:

- Risk and hazard analysis
- Design reviews
- Unit level testing
- Integration testing
- System testing
- Performance testing
- Usability engineering
- Software verification & validation activities
- Cybersecurity and vulnerability analysis

7.2 PERFORMANCE DATA

The following performance tests are done for the combined prostate- subregion segmentation algorithm:

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 segmentations to their 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 testing

With the results from the non-clinical performance testing of the prostate segmentation algorithm being at least as accurate as that of the predicate device, the semi-automatic clinical performance test of the prostate segmentation has not been repeated. The clinical performance test of the subregion 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 at least as accurate as the predicate device was.

7.2.1 Safety implications

The changes made in Quantib Prostate 3.0 do not affect the safety of the device.

8 CONCLUSIONS

By virtue of its intended use, design features, and technological characteristics, Quantib Prostate 3.0 is substantially equivalent to a device that has been approved for marketing in the United States. The performance data shows that Quantib Prostate 3.0 is as safe and effective as the predicate device.