Quantib BV   October 11, 2020
℅ Mrs. Floor van Leeuwen
Quality and Regulatory Manager
Westblaak 106
Rotterdam, Zuid-Holland 3012 KM
NETHERLANDS

Re: K202501
    Trade/Device Name: Quantib Prostate
    Regulation Number: 21 CFR 892.2050
    Regulation Name: Picture archiving and communications system
    Regulatory Class: Class II
    Product Code: LLZ
    Dated: August 27, 2020
    Received: August 31, 2020

Dear Mrs. 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,

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

Indications for Use

510(k) Number *(if known)*
K202501

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.

Quantib Prostate
510(k) Summary

Quantib

1   SUBMITTER

Quantib B.V.
Westblaak 106
3012 KM Rotterdam
Phone: (+31) 108 41 17 49
Contact Person: Floor van Leeuwen
Date Prepared: August 27, 2020

2   DEVICE

Name of Device: Quantib Prostate
Common or Usual Name: Quantib Prostate
Regulation Description: Picture archiving and communication system
Product Code: LLZ
Regulation number: 892.2050
Device Class: II

3   PREDICATE DEVICE

Device: DynaCAD
Manufacturer: Invivo Corporation
510(k) Reg. No: K192200
This predicate has not been subject to a design-related recall.
Product Code: LLZ
Device Class: II

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 segmentation and multi-parametric MRI image registration.

- 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, and segment and analyze potential lesions. This extension will also apply a mathematical operation on the input images to combine information from the MRI sequences into a single combination image.
- An automatic processing module that collects all results for exporting and transferring back to the user.

5   INDICATIONS FOR USE

5.1   INDICATIONS FOR USE QUANTIB PROSTATE

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 PREDICATE DEVICE

DynaCAD

The DynaCAD software consists of the MR Analysis Server software and the viewer workstation software. The MR Analysis Server software, which includes the DynaCAD Breast, DynaCAD Prostate, and DynaCAD PK for other MR Analysis modules, is intended to be used as a post-processing software package designed to provide a reliable means for analyzing MR datasets. The software facilitates the analysis of dynamic and non-dynamic MR datasets to provide study review and additional mathematical and/or statistical analysis. The resulting analysis can be displayed in a variety of formats, including parametric images overlaid onto source MRI images.

The viewer workstation software is intended for use in conjunction with the MR Analysis Server software and facilitates the analysis and presentation of datasets generated by the MR Analysis Server software and incorporates the following functions: Region of Interest (ROI) curve, Pixel of Interest (POI) curve, Report Card, Volume Calculation, Statistical Analysis, 3-D visualization of image series, and DICOM reporting, among other capabilities. DynaCAD software serves as a workflow roadmap tool that organizes and guides the radiologist through the series of sequential tasks that must be performed in order to arrive at a diagnosis. The specific configuration of product features drives the DynaCAD software underlying workflow solution for lesion characterization and reporting. This inherent workflow regimen integrates into the radiologist's existing departmental workflow and can be adapted to fit the needs of each user. In the hands

of a trained physician the information provided by the data analysis could yield information that may assist in the interpretation of dynamic and non-dynamic MR studies.

DynaLOC Breast

The DynaLOC Breast Interventional Planning software module supports the use of interventional breast coils and MR stereotactic localization devices to perform MR-guided breast interventional procedures. Using information from MR images regarding the coordinates of a user-specified region of interest, and fiducial coordinates, the software provides an automatic calculation of the location and depth of the targeted region of interest, such as a lesion or suspected lesion, relative to the interventional device.

DynaLOC Prostate

DynaLOC Prostate Interventional is a computer-based image-guidance accessory for use with commercially available Magnetic Resonance (MR) imaging systems and interventional devices. The application provides the user with patient data processing, visualization and storage functions. It allows image analysis, display and recording of simulated images of a tracked insertion tool, such as a needle guide or sleeve, on a computer monitor or other display that shows images of the target organs and the current and/ or projected path of the interventional instrument. The device is intended to be used by physicians in a clinical setting for treatment planning and guidance for clinical, interventional and/or diagnostic procedures of the prostate.

5.3 INDICATIONS FOR USE COMPARISON

The Indications for Use of Quantib Prostate are partially equivalent to those of DynaCAD.

The Indications for Use of DynaCAD is divided in three sections: DynaCAD, DynaLOC Breast, and DynaLOC Prostate. The partial equivalence between the Indications for Use of Quantib Prostate and DynaCAD is only based on the first section: DynaCAD. The sections about DynaLOC Breast and DynaLOC Prostate do not contain any Indications for Use that are relevant for Quantib Prostate.

The Indications for Use of DynaCAD are broader than that of Quantib Prostate, while the Indications for Use of Quantib Prostate are fully within the range of DynaCAD's Indications for Use. This is confirmed by the comparison of technological characteristics between the two products in Section 6.

As the Indications for Use of Quantib Prostate are fully covered by the Indications for Use of DynaCAD, we conclude that the differences between both products do not raise any questions on the effectiveness and safety of Quantib Prostate compared to DynaCAD.

6 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Item	Quantib Prostate	DynaCAD K192200
Target users *Equivalent*	Trained medical professionals	Trained medical professionals
Anatomical site *Partially equivalent*	Prostate	Any
Where used *Equivalent*	Hospital	Hospital
Human factors *Equivalent*	User can approve or reject results	User can approve or reject results.
	User can inspect and edit prostate segmentation	User can inspect and edit prostate segmentation.
	User can enter PSA value and compute PSA density	User can enter PSA value and compute PSA density
	User can create and update regions of interest (ROIs)	User can create and update regions of interest (ROIs)
	User can add and update annotations (text) to analysis	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 manually set a PI-RADS score using a PI-RADS interactive worksheet
Design *Partially equivalent*	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, Basic image manipulation tools, Thresholding tool User interface to create/update user-generated ROIs.
Performance data		
Non-clinical performance *Partially equivalent*	Bench testing performed to test the functionality of the system. This included characterization of the stand-alone performance of the prostate segmentation algorithm.	Bench testing performed to test the functionality of the system.
Clinical performance *Predicate device has no data to assess equivalency*	Prostate segmentation algorithm was tested in a clinical use context, i.e. as a semi-automatic algorithm after correction by trained clinicians.	No clinical performance data available.
Standards met *Equivalent*	• 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
SW verification and validation *Equivalent*	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	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

Item	Quantib Prostate	DynaCAD K192200
	use.	use.
Compatibility with the environment and other devices *Equivalent*	DICOM compatible	DICOM compatible
Reported measures *Equivalent*	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
Required input *Equivalent*	DICOM compatible data, type of MRI scans: T2-weighted, DWI, ADC, DCE	DICOM compatible data, type of MRI scans: T2-weighted, DWI, ADC, DCE

For some of the technological characteristics compared above a more detailed description on their equivalency follows:

- *Anatomical site:* DynaCAD can load MR images from any anatomical site, amongst which images of the prostate region. Quantib Prostate is only intended for use with MR images from the prostate region. As the use intended for Quantib Prostate is fully covered within the uses possible with DynaCAD, we conclude that this difference does not raise any questions on the effectiveness and safety of Quantib Prostate compared to DynaCAD.
- *Design:* Quantib Prostate includes all design aspects of DynaCAD, and adds the functionality to view biparametric combination images. A biparametric combination image is directly computed by a straightforward mathematical equation from images that are also individually shown in the multi-parametric viewer. Dynacad also provides a viewer for multi-parametric images. Combining these images into a single biparametric combination image does not add new information compared to the original images. Therefore, we conclude that this addition does not raise any questions on the effectiveness and safety of Quantib Prostate compared to DynaCAD.
- *Performance data*
    - *Non-clinical performance:* For both products bench testing was performed to test the functionality of the system and in that sense they are equivalent. For Quantib Prostate the stand-alone performance of the prostate segmentation algorithm was characterized in addition.
    - *Clinical performance:* Clinical performance was tested for the semi-automatic prostate segmentation algorithm in Quantib Prostate. As there are no clinical performance results available for DynaCAD, comparing the performance of a clinician using Quantib Prostate to segment a prostate with a clinician not using Quantib Prostate is a reasonable way to prove safety and effectiveness of the semi-automatic segmentation algorithm.
    As this is additional performance data compared to the performance data available for DynaCAD, we conclude that this does not raise any questions on safety and effectiveness of Quantib Prostate compared to DynaCAD.

7 PERFORMANCE DATA

7.1 STANDARDS MET

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

- ANSI AAMI ISO 14971:2007/(R)2010 – Medical devices - Application of risk management to medical devices
- ANSI AAMI IEC 62304:2006/A1:2016 – Medical device software – Software life cycle processes
- ANSI AAMI IEC 62366-1:2015 – Medical devices- applications of usability engineering to medical devices

7.2 VERIFICATION AND VALIDATION ACTIVITIES

Quantib Prostate has been tested in accordance with Quantib's verification and validation processes and plan, addressing intended use, product claims, requirement specifications and risk management results. The testing results support that all the system requirements have met their pre-defined acceptance criteria.

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

- Risk and hazard analysis
- Design reviews
- Unit level testing
- Integration testing
- System testing
- Performance testing
- Usability engineering

7.3 NON-CLINICAL PERFORMANCE TESTING

Bench testing was done to show that the system is suitable for its intended use and to characterize the stand-alone performance of the prostate segmentation algorithm. The latter is intended to inform the user on the limitations of the prostate segmentation algorithm to facilitate the user in review and editing of the resulting prostate segmentations before further use in the software. Bench testing did not reveal any issues with the system, demonstrating that the performance of Quantib Prostate is as safe and effective as its predicate devices.

7.4 CLINICAL PERFORMANCE TESTING

The prostate segmentation algorithm was tested in a clinical use context. It was concluded that a trained medical professional using Quantib Prostate performs better or equal in prostate segmentation than without use of Quantib Prostate.

7.5 SAFETY IMPLICATIONS

The differences between Quantib Prostate and the predicate device DynaCAD do not affect the safety of the device compared to its predicates. This conclusion is based on:

- Failure mode and effects analysis on the functionality of both products.
- Risk category classification of the software components of both products.
- Level of concern, which is identified to be Moderate for both products.

Quantib Prostate and DynaCAD are both intended to support trained medical professionals in qualitative and quantitative measurement, analysis, and reporting of clinical data. The software does not make diagnoses; it provides quantification results that must be interpreted by a trained medical professional before using them. Quantib Prostate and DynaCAD are both software applications running on off-the-shelve hardware; they do not have hardware components nor are they designed to provide a physical output to the user/patient. In conclusion, Quantib Prostate does not introduce any new safety issues compared to the predicate device DynaCAD

8 CONCLUSIONS

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