QUIBIM S.L.
% John J. Smith, M.D., J.D.
Partner
Hogan Lovells US LLP
555 13th Street, NW
WASHINGTON DC 20005

February 4, 2021

Re: K203582
Trade/Device Name: qp-Prostate
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: December 7, 2020
Received: December 7, 2020

Dear Dr. 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 (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: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*

K203582

Device Name

qp-Prostate

Indications for Use *(Describe)*

qp-Prostate is an image processing software package to be used by trained professionals, including radiologists specialized in prostate imaging, urologists and oncologists. The software runs on a standard "off-the-shelf" workstation and can be used to perform image viewing, processing and analysis of prostate MR images. Data and images are acquired through DICOM compliant imaging devices and modalities. Patient management decisions should not be based solely on the results of qp-Prostate. qp-Prostate does not perform a diagnostic function, but instead allows the users to visualize and analyze DICOM data.

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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510(k) SUMMARY

QUIBIM's qp-Prostate

K203582

CONTACT DETAILS

Submitter

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Date Prepared:

January 28, 2021

DEVICE INFORMATION

Name of Device: qp-Prostate

Common or Usual Name: PACS

Classification Name: 892.2050 Picture archiving and communications system (LLZ)

Regulatory Class: Class II

Classification Panel: Radiology

LEGALLY MARKETED PREDICATE DEVICE

- Manufacturer's name: OLEA Medical (93 avenue des Sorbiers, Zone Athelia IV La Ciotat 13600, France)
- Device's trade name: Olea Sphere v3.0
- 510(k) number: K152602
- Product code: LLZ

INTENDED USE / INDICATIONS FOR USE

qp-Prostate is an image processing software package to be used by trained professionals, including radiologists specialized in prostate imaging, urologists and oncologists. The software runs on a standard "off-the-shelf" workstation and can be used to perform image viewing, processing and analysis of prostate MR images. Data and images are acquired through DICOM compliant imaging devices and modalities. Patient management decisions should not be based solely on the results of qp-Prostate. qp-Prostate does not perform a diagnostic function, but instead allows the users to visualize and analyze DICOM data.

DEVICE DESCRIPTION

qp-Prostate is a medical image viewing, processing and analyzing software package for use by a trained user or healthcare professional, including radiologists specialized in prostate imaging, urologists and oncologists. These prostate MR images, when interpreted by a trained physician, may yield clinically useful information.

qp-Prostate consists of a modular platform based on a plug-in software architecture. Apparent Diffusion Coefficient (ADC) post-processing and Perfusion – Pharmacokinetics post-processing (PKM) are embedded into the platform as plug-ins to allow prostate imaging quantitative analysis.

The platform runs as a client-server model that requires a high-performance computer installed by QUIBIM inside the hospital or medical clinic network. The server communicates with the Picture Archiving and Communication System (PACS) through DICOM protocol. qp-Prostate is accessible through the web browser (Google Chrome or Mozilla Firefox) of any standard “off-the-shelf” computer connected to the hospital/center network.

The main features of the software are:

1. Query/Retrieve interaction with PACS;
2. Apparent Diffusion Coefficient (ADC) post-processing (MR imaging);
3. Perfusion – Pharmacokinetics (PKM) post-processing (MR imaging);
4. DICOM viewer; and
5. Structured reporting.

The software provides MR imaging analysis plug-ins to objectively measure different functional properties in prostate images:

1) The software can communicate with any Picture Archiving Communications System (PACS) through the DICOM standard. This communication includes standard Query/Retrieve DICOM operations in order to receive prostate MR image studies in qp-Prostate. Once the complete prostate MR study has been received, qp-Prostate will check the available sequences. For a successful launch of qp-Prostate, the study must include at least:

-the T2-weighted MR sequence and the Diffusion Weighted Imaging (DWI) or
-the T2-weighted MR sequence and the Dynamic Contrast Enhanced (DCE) or

-the T2-weighted MR sequence, the DWI and the DCE.

2) If the DWI sequence is available and it complies with the required acquisition protocol, the Diffusion ADC analysis will be launched. Imaging processing steps, such as spatial smoothing and motion correction between the different b-values are proposed before applying the mono-exponential model for ADC calculation. The Diffusion-ADC post-processing and analysis plugin for prostate MR imaging calculates a parameter related to the degree of water molecules mobility in tissues. The Apparent Diffusion Coefficient (ADC)[s/mm^2] is given in order to evaluate the diffusion signal decay in regions. The ADC is calculated by applying the mono-exponential model of the diffusion signal, assessing the signal attenuation that occurs at least at two different b values. The final result of the DWI workflow includes ADC parametric maps, which represent the ADC value for each voxel of the image.

3) If the DCE sequence is available and it complies with the required acquisition protocol, the Perfusion analysis will be launched. Imaging processing steps, such as spatial smoothing, motion correction and Arterial Input Function (AIF) selection are proposed before applying the standard Tofts model with one input and two compartments for K^{trans}, k_{ep} and v_e calculation. The Perfusion – Pharmacokinetics post-processing and analysis plugin for prostate MR imaging calculates parameters related to the vascular environment of the tissue, which are based on the quantitative pharmacokinetic assessment of Dynamic Contrast-Enhanced Magnetic Resonance Images (DCE-MRI). The transfer constant (K^{trans})[min^{-1}], extraction rate (k_{ep}) [min^{-1}] and extra-vascular and extra-cellular volume (v_e) [%] are given in order to evaluate the leakage of injected contrast media from intra-vascular to interstitial space. The final results of the DCE workflow include K^{trans}, k_{ep} and v_e parametric maps, which represent perfusion for each voxel of the image.

4) The software includes a DICOM viewer to improve the review process of a single study and its related image sequences. The viewer has basic image manipulation and segmentation capabilities and advanced segmentation ones for prostate.

5) The software includes a Structured Reporting option for filling a standard PI-RADS® v2.1 template [Prostate Imaging Reporting and Data System Version 2.1: 2019 Update of Prostate Imaging Reporting and Data System Version 2. American College of Radiology].

qp-Prostate does not perform a diagnostic function, but instead allows the radiologist to visualize and analyze DICOM data with the possibility of verifying the quality and editing the output of each step of the process.

COMPARISON TO PREDICATE DEVICE

The subject and predicate devices are based on the following same technological elements:

- Both devices work with DICOM 3.0 images retrieved from PACS systems, and can export data back to those PACS systems.
- Both have integrated slice views with MPR, segmentation and ROI tools, and image filtering.
- Both devices perform study management and structured report generation.

- Both uniquely identify users and maintain audit trails of user actions.
- Both have a modular architecture for analysis tools and include modules for perfusion and diffusion for MR cases.

The following technological differences exist between the subject and predicate devices:

- Olea Sphere can import and export to the local file system, whereas qp-Prostate does not.
- Olea Sphere can perform perfusion calculations for both MR and CT, whereas qp-Prostate only does so for MR data.
- qp-Prostate software only includes two analysis modules for perfusion (Perfusion – Pharmacokinetics, PKM) and diffusion (Diffusion - ADC) calculations, whereas Olea Sphere includes more modules.
- qp-Prostate software is indicated only for prostate MR images whereas OLEA covers more anatomical areas, including prostate.

Taken individually and together, these differences do not affect the substantial equivalence; both products are still using the same technological basis. Software validation and verification testing, as well as performance data, confirm that the qp-Prostate functionalities do not raise different questions of safety or effectiveness compared to the predicate, and support substantial equivalence.

A table comparing the key features of the subject and predicate devices is provided below.

Table 1. Comparison of key features of the subject (qp-Prostate, QUIBIM) and the predicate device (OLEA Sphere 3.0, OLEA Medical)

FEATURE	qp-Prostate	Olea Sphere V3.0 K152602
REGULATORY DATA		
Regulatory Class	II	II
Regulation name	Picture archiving and communications system (PACS)	Picture archiving and communications system (PACS)
Regulation number	21 CFR 892.2050	21 CFR 892.2050
Classification Panel	Radiology	Radiology
Product code	LLZ	LLZ
Manufacturer	QUIBIM	Olea Medical
FDA clearance	-	K152602
INTENDED USE		
Indications for use	qp-Prostate is an image processing software package to be used by trained professionals, including	Olea Sphere V3.0 is an image processing software package to be used by trained professionals

FEATURE	qp-Prostate	Olea Sphere V3.0 K152602
	radiologists specialized in prostate imaging, urologists and oncologists. The software runs on a standard "off-the-shelf" workstation and can be used to perform image viewing, processing and analysis of prostate MR images. Data and images are acquired through DICOM compliant imaging devices and modalities. Patient management decisions should not be based solely on the results of qp-Prostate. qp-Prostate does not perform a diagnostic function, but instead allows the users to visualize and analyze DICOM data.	including, but not limited to, physicians and medical technicians. The software runs on a standard "off-the-shelf" workstation and can be used to perform image viewing, processing, image collage and analysis of medical images. Data and images are acquired through DICOM compliant imaging devices and modalities.
CHARACTERISTICS		
Supported image format	DICOM 3.0	DICOM 3.0
Type of scans	MR	MR, CT
Data import	PACS	PACS or file system
Data export	PACS	PACS or file system
Image loading and saving	Yes	Yes
Integrated slice viewer	Yes	Yes
Multi-planar	Yes	Yes
MPR/3D	Yes	Yes
Segmentation tools	Yes	Yes
ROI tools	Yes	Yes
Image Processing	Yes	Yes
Study Management tools	Yes	Yes
Structured report generation	Yes	Yes
License Management System	Yes	Yes
Unique user log-in and password	Yes	Yes
User audit trails	Yes	Yes
Modular analysis plug-ins	Yes	Yes

FEATURE	qp-Prostate	Olea Sphere V3.0 K152602
Intended use environment	Hospitals / imaging centers or clinics	Hospitals / imaging centers or clinics
Intended user	Radiologists specialized in prostate imaging, urologists and oncologists.	Trained professionals including but not limited to physicians and medical technicians
Intended patient population	Any patient for which PACS MR prostate data exists.	Any patient for which PACS data exists.
Image post-processing and analysis plugins	*Not included*	DCE (for MR Imaging) Kinetics – semi quantitative maps (AUC, Peak enhancement map, Peak percentage enhancement, Time to maximum enhancement, Washin, Washout, Relative washout, Signal Enhancement Ratio)
	DCE (for prostate MR imaging) Perfusion – Pharmacokinetics Modelling (K^{trans} [min^{-1}], k_{ep} [min^{-1}], v_e [%])	DCE (for MR imaging) Permeability – Quantitative parameter maps (K^{trans}, k_{ep}, V_p, v_e, signal to concentration time curve conversion with fixed blood and tissue T1 values)
	Not included	DWI (for MR Imaging) Intra – Voxel Incoherent Motion IVIM (ADC, D, D*, f)
	DWI (for MR Imaging) Apparent Diffusion Coefficient (ADC [mm^2/s])	DWI (for MR Imaging) Apparent Diffusion Coefficient (ADC)
	Not included	Yes (T1 and T2 Mapping)
	Not included	Metabolic (hepatic fat fraction FF)

Thus, qp-Prostate device is substantially equivalent to the Olea Sphere V3.0 (K152602) from OLEA Medical.

PERFORMANCE DATA

PERFORMANCE TESTING - BENCH

The following bench testing was performed on the subject device per the following draft guidance: "Technical Performance Assessment of Quantitative Imaging in Device Premarket Submissions" (April 19, 2019) for the unitary validation of the different parts that constitute qp-

Prostate. qp-Prostate is aimed for diffusion and perfusion analysis of prostate MR cases, providing quantitative information useful to assist the professional in completing the prostate structured report template.

One of tests is the analysis of digital reference objects (DROs) proposed by QIBA, available for DWI and DCE, considered as ground truth. For both Perfusion-Pharmacokinetics (PKM) and Diffusion-ADC analysis modules, DROs, including presence and absence of noise modeling, are used for technical performance evaluation.

Table 2. qp-Prostate's Performance Bench Testing for Diffusion and Perfusion Analysis Modules

qp-Prostate functionality	Test type	Dataset
Diffusion – ADC analysis module	Digital Reference Object Analysis (Diffusion – ADC)	QIBA's Diffusion Weighted Imaging (DWI) Digital Reference Object (DRO)
Perfusion - Pharmacokinetics analysis module	Digital Reference Object Analysis (Perfusion – Pharmacokinetics)	QIBA's Dynamic Contrast-Enhanced (DCE) MR perfusion DRO

PERFORMANCE TESTING - CLINICAL

A dataset of prostate clinical cases was used for the validation of the algorithms integrated in qp-Prostate v1.0.0 such as Spatial Smoothing algorithm, Registration algorithm, Automated Prostate Segmentation algorithm, Motion Correction algorithm and automated AIF selection algorithm.

The other assessment is the comparison against the predicate device (OLEA Sphere, v3.0, K152602), using 157 clinical cases of prostate MRI. The dataset includes cases from different three major MRI vendors: Siemens, GE and Philips, magnetic field of 3T and 1.5T cases and different technical parameters that make up the broad spectrum of cases allowed in our recommended protocol (T2w + DWI + DCE).

Table 3. qp-Prostate's Performance Clinical Testing and Comparison with the Predicate Device

qp-Prostate functionality	Test type	Dataset
Motion Correction algorithm	Performance testing with prostate MR cases	155 DCE-MR and DWI-MR prostate sequences acquired form 155 different patients in different machines with multiple acquisition protocols
Registration algorithm	Performance testing with	112 T2-Weighted MR, DCE-MR and 108 DWI-MR prostate sequences acquired from different

	prostate MR cases	patients in different machines with multiple acquisition parameters
Spatial Smoothing algorithm	Performance testing with prostate MR cases	51 transverse T2-weighted, DCE-MR and DWI-MR prostate sequences acquired from 51 different patients in different machines with multiple acquisition protocols
AIF selection algorithm	Performance testing with prostate MR cases	242 DCE-MR prostate sequences acquired from 242 different patients in different machines with multiple acquisition protocols
Prostate Segmentation algorithm	Performance testing with prostate MR cases	243 transverse T2-weighted MR prostate sequences acquired from 243 different patients in different machines with multiple acquisition protocols.
Comparison to the Predicate Device (OLEA Sphere, v3.0, K152602)	Comparison to predicate device	157 T2-weighted MR, DCE-MR and 141 DWI-MR prostate sequences acquired form different patients in different machines with multiple acquisition protocols

SOFTWARE VERIFICATION & VALIDATION

qp-Prostate software was developed according to FDA recognized consensus standards for software development. Software verification and validation was performed following V&V plans and protocols verifying that product specifications were met.

The tests results demonstrate that qp-Prostate functioned as intended, is acceptable for clinical use, and is as safe and effective as its predicate device, without introducing new questions of safety and efficacy.

CONFORMANCE STANDARDS

The qp-Prostate complies with the following FDA recognized consensus standards:

- ISO 62304:2006/A1:2016 Medical device software - Software life cycle processes
- ISO 14971 Medical devices - Applications of risk management to medical devices
- ISO 82304:2016 Health software - Part 1: General requirements for product safety
- IEC 60601-1 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests
- IEC 62366 Medical devices - Part 1: Application of usability engineering to medical devices
- ISO 80002 Medical device software – Part 1: Guidance on the application of ISO 14971 to medical device software

In addition, the device also complies with the following consensus standards:

- ISO 13485 Medical devices — Quality management systems — Requirements for regulatory purposes

CONCLUSIONS

qp-Prostate is as safe and effective as the Olea Sphere v3.0. qp-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 qp-Prostate and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that qp-Prostate is as safe and effective as the OLEA Sphere v3.0. Thus, qp-Prostate is substantially equivalent.