



Mint Labs, Inc., d/b/a. QMENTA  
% Paulo Rodrigues  
CTO, Co-Founder  
QMENTA Imaging S.L.  
C/ Roger de Lluria 46, Pral. 1<sup>a</sup> 08009  
Barcelona, Cataluna 08009  
SPAIN

June 16, 2021

Re: K202718

Trade/Device Name: QMENTA Care Platform Family  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Medical image management and processing system  
Regulatory Class: Class II  
Product Code: LLZ  
Dated: March 26, 2021  
Received: April 1, 2021

Dear Paulo Rodrigues:

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](mailto: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)  
K202718

Device Name  
QMENTA Care Platform Family

### Indications for Use (Describe)

QMENTA Care Platform Family is a software medical imaging system used to receive DICOM images and textual reports, organize and store them in an internal format, and to make that information available across a network via web and customized user interfaces. QMENTA Care Platform Family consists of two components:

1. A Storage/archiving server for the retrieval of DICOM images from CT and MR modality data, and also PET/CT data from PACS and/or OS-based file storage.
2. A workflow server that allows to integrate legally marketed applications for clinical use into the QMENTA Care Platform Family. The applications are geared toward specific types of image analysis and are marketed with corresponding names.

The results may be saved to a DICOM image file and may be further visualized on an imaging workstation.

QMENTA Care Platform Family is designed to aid suitably qualified physicians, who will base their diagnoses on training and protocols that do not necessarily rely on image maps or image quantifications.

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.

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## SECTION 5. 510(K) SUMMARY

### Submitter:

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#### Contact Person:

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 Phone: +34 933 282 007

Date prepared: September, 09, 2020

### Device:

<b>Trade/Proprietary Name:</b>	Mint Labs, Inc., d/b/a. QMENTA - QMENTA Imaging S.L.
<b>Common Name:</b>	QMENTA CARE PLATFORM FAMILY
<b>Classification Name:</b>	Picture archiving and communication systems to medical image management and processing system 21 CFR 892.2050
<b>Classification Regulations:</b>	Class II
<b>Product Code:</b>	LLZ
<b>Review panel:</b>	Radiology
<b>Performance standards:</b>	None established under Food Drug and Cosmetic Act

### Predicate device:

The QMENTA Platform Product Family is one product with a predicate. The QMENTA Platform Family is a storage/archiving server for the retrieval of DICOM images from CT and MR modality data, and also PET/CT data from PACS and/or OS-based file storage; and also, a workflow server that may run image processing workflows on image studies. These



image processing workflows can be different “plugged in” modules from different manufacturers.

**Predicate**

Characteristic	Predicate Device	Proposed Device	Explanation of differences
<b>Manufacturer</b>	Blackford Analysis LTD	Mint Labs, Inc., d/b/a. QMENTA - QMENTA Imaging S.L.	-
<b>Device Name</b>	Blackford Analysis Registration Product Family	QMENTA Care Platform Family	-
<b>510(k) number</b>	K142337	N/A	-
<b>Device Classification</b>	Class II	Class II	-
<b>Regulation Nº</b>	892.2050	892.2050	-
<b>Product Code</b>	LLZ	LLZ	-
<b>Indications for use:</b>	<p><b>The Blackford Registration Product Family</b> consists of two components:</p> <ol style="list-style-type: none"> <li>1. A Workflow Server that calculates DICOM registration objects from CT and MR modality data, and also PET/CT data via using the CT data for registration.</li> <li>2. A localizer tool that works across studies, or series in the same study within a different frame of reference.</li> </ol> <p>The first intended clinical use, when reading studies of the above modalities, is to aid navigation through, and comparative interpretation of, a target</p>	<p><b>QMENTA Care Platform Family</b> is a software medical imaging system used to receive DICOM images and textual reports, organize and store them in an internal format, and to make that information available across a network via web and customized user interfaces. <b>QMENTA Care Platform Family</b> consists of two components:</p> <ol style="list-style-type: none"> <li>1. <b>A Storage/archiving server</b> for the retrieval of DICOM images from CT and MR modality data, and also PET/CT data from PACS</li> </ol>	<p>The devices are highly similar in their indications for use since they both focus on the calculation of DICOM objects from CT and MR modality data, and also PET/CT data.</p> <p>Both devices include a Workflow Server component, that performs the image processing operations of the DICOM objects.</p> <p>Blackford includes a localizer tool to help the user</p>

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	<p>series with respect to a source series. Normally, the source series will be within a current study and the target series will be within a prior study. However they may also be within the same study but have a different frame of reference. Aiding navigation may include, but is not limited to, indicating corresponding anatomical locations, synchronized scrolling, matching orientations and/or reference lines in reformatted series and fusing two images from source and target series.</p> <p>The second clinical use is to aid presentation of change between cross-sectional radiographic studies to clinical colleagues and patients.</p> <p>Registration-aided interpretation of images should be carried out by a suitably qualified physician, who will base their diagnoses on training and protocols that do not necessarily rely on registration for navigation</p>	<p>and/or OS-based file storage.</p> <p>2. <b>A workflow server</b> that allows to integrate legally marketed applications for clinical use into the QMENTA Care Platform Family. The applications are geared toward specific types of image analysis and are marketed with corresponding names.</p> <p>The results may be saved to a DICOM image file and may be further visualized on an imaging workstation.</p> <p><b>QMENTA Care Platform Family</b> is designed to aid suitably qualified physicians, who will base their diagnoses on training and protocols that do not necessarily rely on image maps or image quantifications.</p>	<p>navigate through studies, or series in the same study. Similarly, QMENTA Care provides a storage and archiving server where the user can navigate through the studies or series within a study.</p>
<p><b>Use Scenario</b></p>	<p>Registration-aided interpretation of images should be carried out by a suitably qualified physician, who will base their diagnoses on training and</p>	<p>QMENTA Care Platform Family is designed to aid suitably qualified physicians, who will base their diagnoses on training and protocols that do not</p>	<p>Not a clinically significant difference.</p>

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	protocols that do not necessarily rely on registration for navigation.	necessarily rely on image maps or image quantifications.	
<b>Technological Characteristics</b>	<p><b>Multiple applications</b> Hosts and manages a portfolio of Blackford® and Platform Partner products, configured and managed centrally, supporting automated or triggered processing of imaging applications and AI algorithms.</p>	<p><b>Multiple Applications</b> Additional legally marketed applications for clinical use can be "plugged in" into the QMENTA Care Platform Family. The applications are geared toward specific types of image analysis and are marketed with corresponding names.</p>	Not a clinically significant difference.
	<p><b>Flexible hosting and cloud deployment</b> Flexible hosting allows clinical applications to be locally hosted on VM or Docker containers. Cloud deployment enables studies to be routed to separate resource in the cloud, minimizing dataflow</p>	<p><b>Flexible hosting and cloud deployment</b> The "plugged in" clinical applications are hosted on VM or Docker containers. Studies are routed to separate resources in the cloud, minimizing dataflow.</p>	Not a clinically significant difference – hosted using resources in the cloud.
	<p><b>Fully DICOM compliant</b> DICOM compliant and integrated with DICOM modality worklist to pre-fetch prior studies for analysis.</p>	<p><b>Fully DICOM compliant</b> DICOM image studies retrieved from PACS and/or OS-based file storage. From a workflow perspective, QMENTA Care can operate as a computing appliance that is capable of supporting DICOM file transfer for input and output of results.</p>	Not a clinically significant difference.
	<p><b>Configurable dataflow</b> Configurable dataflow management offers multiple adaptable SCPs that maximize data ingestion speed, customizable AE titles for manual triggering, and</p>	<p><b>Configurable dataflow</b> QMENTA Care offers configurable dataflow management, where image studies can be transferred from multiple SCPs into the Storage/Archiving server. Then images can be</p>	Not a clinically significant difference.

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	<p>comprehensive patient consolidation from multiple sources.</p>	<p>automatically processed by the configured image processing applications, and results can be automatically transferred back to a third party DICOM workstation or PACS.</p> <p>QMENTA PACS Nexus is a small application that runs on a local workstation inside the hospital network and automates the task of exporting images to the QMENTA Care Platform and retrieving the results.</p>	
	<p><b>Relevancy Engine</b>          Relevancy engine determines which studies to send each clinical application and collates descriptor knowledge from all deployments. It automates the process of matching incoming study information with the appropriate application, processes the data, and ensures results are quickly sent back to the right system.</p>	<p><b>Protocol Adherence Engine</b>          The protocol adherence engine determines if studies follow the configured requirements for a clinical application, taking into account description knowledge and image parameters available in DICOM objects, e.g. number of timepoints, consistent spacing, etc.</p>	<p>Not a clinically significant difference.</p>
	<p>Blackford Curated Marketplace™ provides a vetted curated marketplace of regulatory approved medical imaging analysis applications and AI algorithms accessed via Blackford Platform.</p>	<p>QMENTA Software Development Kit provides the possibility of integrating curated legally marketed third-party applications for clinical use accessed via QMENTA Care Platform Family.</p>	<p>Not a clinically significant difference.</p>





## **Substantial equivalence to the predicate**

The subject and predicate device are software programs for the management of multiple imaging applications and AI algorithms, in one system in the cloud.

Both devices provide access to medical imaging analysis and artificial intelligence algorithms incorporated as software packages for use with DICOM objects from CT, MR modalities, and also PET/CT data.

While the subject device's indications for use differ slightly from the predicate device, both devices are intended to simplify the deployment and management of medical imaging applications and AI algorithms.

Both devices are intended for use by radiologists and other clinicians for the purpose of extracting actionable information from radiological medical images.

### **Device description:**

**QMENTA Care Platform Family (QMENTA Care)** is a software medical imaging system that runs on standard computer hardware that may compute legally marketed applications for clinical use based on DICOM images captured via MR, CT and PET modalities.

These actions include:

- Retrieval of MR, CT and PET DICOM image studies from PACS and/or OS-based file storage
- Computation of legally marketed applications for clinical use
- Generation of reports summarizing the computations performed

The resulting output may be provided in a standard DICOM format as additional MR series with possible computed outputs (image overlays, numerical reports, and/or other results) that can be displayed on third-party DICOM workstations and Picture Archive and Communications Systems (PACS).

From a workflow perspective, QMENTA Care can operate as a computing appliance that is capable of supporting DICOM file transfer for input and output of results.

The legally marketed applications for clinical use can be "plugged in" into the QMENTA Care Platform Family. The applications may be geared toward specific types of image analysis and may be marketed with corresponding names.

### **Indications for use**

QMENTA Care Platform Family is a software medical imaging system used to receive DICOM images and textual reports, organize and store them in an internal format, and to make that information



available across a network via web and customized user interfaces. QMENTA Care Platform Family consists of two components:

1. A Storage/archiving server for the retrieval of DICOM images from CT and MR modality data, and also PET/CT data from PACS and/or OS-based file storage.
2. A workflow server that allows to integrate legally marketed applications for clinical use into the QMENTA Care Platform Family. The applications are geared toward specific types of image analysis and are marketed with corresponding names.

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QMENTA Care Platform Family is designed to aid suitably qualified physicians, who will base their diagnoses on training and protocols that do not necessarily rely on image maps or image quantifications.

#### **Performance data**

All product specifications were verified and validated. Testing was performed according to internal company procedures.

Software testing and validation were conducted according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to release. Test results support the conclusion that actual device performance satisfies the design intent.

Verification and validation testing was completed in compliance with the following standards and guidance documents:

- ISO 14971:2012, Medical devices – application of risk management to medical devices
- AAMI ANSI IEC 62304:2006, Medical device software – Software life cycle processes
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff” (January, 2002)
- AAMI ANSI IEC 62366:2007, Medical devices – Application of usability engineering to medical devices



The following quality assurance measures were applied to the QMENTA Care Platform Family product:

- Risk Analysis
- Requirements Review
- Design Reviews
- Testing on unit level
- Integration testing
- Performance testing

Results from internal verification and validation testing performed in accordance with QMENTA Imaging design control processes confirm that QMENTA Care Platform Family product specifications have been met. Testing described in this 510(k) consists of verification of all design input requirements and product specifications. All clinical input requirements were validated. Supporting documentation is included in this 510(k) Premarket Notification and supports the claims of substantial equivalence to the predicate device. Cybersecurity is also addressed in this submission. The subject of this submission, QMENTA Care Platform Family, did not require animal testing, biological testing, sterility testing, electrical safety testing or electromagnetic compatibility testing.

The subject of this premarket submission, QMENTA Care Platform Family, did not require clinical studies to support substantial equivalence.

The QMENTA Care Platform Family risk analysis was completed and risk control measures were implemented to mitigate unacceptable hazards.

Additionally, usability testing was performed as part of the HFE/Usability Validation process including a minimum of 15 participants. All the participants were selected to reflect the intended use population categories.

**Conclusions:**

By virtue of its intended use and physical and technological characteristics, QMENTA CARE PLATFORM FAMILY® is substantially equivalent to a device that has been approved for marketing in the United States.

The performance data shows that QMENTA CARE PLATFORM FAMILY® is as safe and effective as the predicate device.