Phantomics Inc.
% Milly Milly
Regulatory Affairs Consultant
KMC, Inc.
Room no. 1709, 123, Digital-ro 26-gil, Guro-gu
Seoul, 08390
REPUBLIC OF KOREA

Re: K211432
Trade/Device Name: Myomics Q
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: September 13, 2021
Received: October 4, 2021

Dear Milly Milly:

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,

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)*
K211432

Device Name
Mynomics Q

Indications for Use *(Describe)*
Myomics Q is intended to be used for viewing, post-processing and analysis of cardiac magnetic resonance (MR) images in a Digital Imaging and Communications in Medi-cine (DICOM) Standard format. It enables:
- Importing cardiac MR images in DICOM format.
- Supporting clinical diagnostics by analysis of cardiac MR images using display functionality such as panning, windowing, zooming through series/slices of the images.*
- Supporting clinical diagnostics analysis of the heart in cardiac MR images and signal intensity.
- Software package is designed to support the physician-to-physician compliance assessment, document and follow up heart disease by cardiac MRI.

It shall be used by qualified medical professionals, experienced in examining and eval-uating cardiovascular MR images, for the purpose of obtaining diagnostic information as part of a comprehensive diagnostic decision-making process. This device is a soft-ware application that can be used as a stand-alone product or in a network environment.

The target population for the device is not restricted, however the image acquisition by a cardiac MR scanner may limit the use of the device for certain sectors or the public.

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

This summary of 510(k) for K211432 –safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: Sept 13, 2021

1. INFORMATION

1.1 Submitter Information

- Submitter Name: Phantomics Inc.
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  : B-1224, 247, Gonghang-daero, Gangseo-gu, Seoul, 07803, Republic of Korea
- Telephone Number: +82-2-6347-2019
- Fax: +82-504-329-2510

1.2 Contact Person

- Name: Milly (Consultant / KMC, Inc.)
- Address: Rm. No. 1709, 123, Digital-ro 26-gil, Guro-gu, 08390, Republic of Korea
- Telephone Number: +82-70-8965-5554
- Fax: +82-2-2672-0579
- E-mail: milly@kmcerti.com

2. DEVICE INFORMATION

2.1 Trade Name / Proprietary Name: Myomics Q

2.2 Common Name: Image Processing System

2.3 Classification Name: Medical Image Management and Processing System

2.4 Product Code: LLZ

2.5 Classification Regulation: 21CFR 892.2050

2.6 Device Class: Class II

(special controls; voluntary standards—Digital Imaging and Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG) Std., Society of Motion Picture and Television Engineers (SMPTE) Test Pattern)

2.7 Classification Panel: Radiology

3. PREDICATE DEVICE

Item	Predicate Device	Reference Device
Manufacturer	Circle Cardiovascular Imaging Inc.	Circle Cardiovascular Imaging Inc.
Device Name (Trade Name)	cmr42	cvi42
510(k) Number	K082628	K141480

4. SUBJECT DEVICE DESCRIPTION

Myomics Q is software application for evaluating cardiovascular images in a DICOM Standard format. The software can be used as a stand-alone product that can be integrated into a hospital or private practice environment. This device has a graphical user interface which allows users to analyze cardiac MR Images qualitatively and quantitatively.

5. INDICATIONS FOR USE

Myomics Q is intended to be used for viewing, post-processing and analysis of cardiac magnetic resonance (MR) images in a Digital Imaging and Communications in Medicine (DICOM) Standard format. It enables:

- Importing cardiac MR images in DICOM format.
- Supporting clinical diagnostics by analysis of cardiac MR images using display functionality such as panning, windowing, zooming through series/slices of the images.*
- Supporting clinical diagnostics analysis of the heart in cardiac MR images and signal intensity.
- Software package is designed to support the physician-to-physician compliance assessment, document and follow up heart disease by cardiac MRI.

It shall be used by qualified medical professionals, experienced in examining and evaluating cardiovascular MR images, for the purpose of obtaining diagnostic information as part of a comprehensive diagnostic decision-making process. This device is a software application that can be used as a stand-alone product or in a network environment.

The target population for the device is not restricted, however the image acquisition by a cardiac MR scanner may limit the use of the device for certain sectors or the public.

6. SUBSTANTIAL EQUIVALENCE

-	Subject Device	Primary Device	Reference Device	Equivalence Result
Manufacturer	Phantomics Inc.	Circle Cardiovascular Imaging Inc.	Circle Cardiovascular Imaging Inc.	Unique Information
Device Name	Myomics Q	cmr42	cvi42	
510(k) Number	K211432	K082628	K141480	
Regulation Number	21CFR892.2050	21CFR892.2050	21CFR892.2050	☑ Same ☐ Similar ☐ Different
Regulation Name	Medical Image Management and Processing System	Medical Image Management and Processing System	Medical Image Management and Processing System	☑ Same ☐ Similar ☐ Different
Classification	Class II	Class II	Class II	☑ Same ☐ Similar ☐ Different
Product Code	LLZ	LLZ	LLZ	☑ Same ☐ Similar ☐ Different
Indication for use	Myomics Q is intended to be used for viewing, post-processing and analysis of cardiac magnetic resonance (MR) images in a Digital Imaging and Communications in Medicine (DICOM) Standard format. It enables: • Importing cardiac MR images in DICOM format.	cmr 42 is intended to be used for viewing, post-processing and analysis of cardiac magnetic resonance (MR) images in a Digital Imaging and Communications in Medicine (DICOM) Standard format. It enables;	Cvi42 vascular analysis add-on is an image analysis software package add-on for evaluating CT and MR images of blood vessels. Combining digital image processing and visualization tools such as multiplaner reconstruction (MPR), thin/think maximum intensity projection (MIP)	☐ Same ☑ Similar ☐ Different

	• Supporting clinical diagnostics by analysis of cardiac MR images using display functionality such as panning, windowing, zooming through series/slices of the images.* • Supporting clinical diagnostics analysis of the heart in cardiac MR images and signal intensity. • Software package is designed to support the physician-to-physician compliance assessment, document and follow up heart disease by cardiac MRI. It shall be used by qualified medical professionals, experienced in examining and evaluating cardiovascular MR images, for the purpose of obtaining diagnostic	• Importing Cardiac MR Images in DICOM format • Supporting clinical diagnostics by qualitative analysis of the cardiac MR images using display functionality such as panning, windowing, zooming, navigation through series/slices and phases. • Supporting clinical diagnostics by quantitative measurement of the heart and adjacent vessels in cardiac MR images, specifically distance, area, volume and mass • Supporting clinical diagnostics by using area and volume measurements for measuring LV function and derived parameters cardiac output and cardiac index in long axis and short axis cardiac MR images • Flow quantifications based on velocity encodes images It shall be used by qualified medical	thin and think, inverted MIP thin and think, volume rendering technique (VRT), curved planner reformation, processing tools such as bone removal (based on both single energy and dual energy) table removal and evaluation tools (vessel centerline calculation, lumen calculation, stenosis calculation) and reporting tools (lesion location, lesion characteristics) and key images), the software package is designed to support the physician in conforming the presence or absence of physician identified lesion in blood vessels and evaluation, documentation and follow up of any such lesions. It shall be used by qualified medical professionals, experienced in examining and evaluating cardiovascular CT or MR images, for the purpose of obtaining diagnostic information as part of a comprehensive diagnostic decision-making process. cvi42 is a software application that can	

	information as part of a comprehensive diagnostic decision-making process. This device is a software application that can be used as a stand-alone product or in a network environment. The target population for the device is not restricted, however the image acquisition by a cardiac MR scanner may limit the use of the device for certain sectors or the public.	professionals, experienced in examining and evaluating cardiovascular MR images, for the purpose of obtaining diagnostic information as part of a comprehensive diagnostic decision-making process. cmr 42 is a software application that can be used as a standalone product or in a networked environment. The target population for the cmr42 is not restricted, however the image acquisition by a cardiac magnetic resonance scanner may limit the use of the device for certain sectors of the general public. cmr 42 shall not be used to view or analyze images of any part of the body except the cardiac magnetic resonance images acquired from a cardiovascular magnetic resonance scanner.	be used as a stand-alone product or in a networked environment. The target population for the cvi42 is not restricted.	
Image from all MRI	Yes	Yes	Yes	☑ Same ☐ Similar ☐ Different

OS (Operating System)	Window	Mac OS, Microsoft, Windows	Mac OS, Microsoft, Windows	☐ Same ☑ Similar ☐ Different
DICOM Compliant networking	Yes	Yes	Yes	☑ Same ☐ Similar ☐ Different
Display of Images	Study & Series	Study & Series	Study & Series	☑ Same ☐ Similar ☐ Different
Store images	File Format: dcm, json, csv, nii	File Format: PDF, XML	File Format: PDF, XML	☐ Same ☐ Similar ☑ Different
Quantities assessment of cardiac function	Yes (Myocardiac)	Yes (Myocardiac and Blood Flow)	Yes (Myocardiac and Blood Flow)	☐ Same ☐ Similar ☑ Different
Corresponding Tool	Yes (Contour)	Yes (Contour)	Yes (Contour)	☑ Same ☐ Similar ☐ Different
Reports containing visualization of images and quantitative parameters	T1, T2 T1 & T2 Mapping Late Gd Enhancement (LGE)	T1, T2 T1 & T2 Mapping Late Gd Enhancement (LGE) Perfusion Flow Analysis	T1, T2 T1 & T2 Mapping Late Gd Enhancement (LGE) Perfusion Flow Analysis	☐ Same ☐ Similar ☑ Different

1) Same points between the subject device and the predicate device

Same Items	Description
Regulation Number	The proposed regulation number is "21CFR892.2050". The Regulation is related to the Medical Image Management and Processing System. It is the same point between the subject device (Myomics Q) and the predicate device (cmr42) including the reference device (cvi42).
Regulation Name	The proposed regulation name is Medical Image Management and Processing System in accordance with 21CFR892.2050. The subject device and predicate device are an image analysis software for evaluating cardiac MR images. It is the same point between the subject device (Myomics Q) and the predicate device (cmr42) including the reference device (cvi42).
Classification	In accordance with same regulation number (21CFR892.2050), FDA provide the regulatory classification. It is Class II and same point between the subject device (Myomics Q) and the predicate device (cmr42) including the reference device (cvi42).
Product Code	The proposed product code of the subject device is "LLZ". It is the same product code with the predicate device (cmr42) including the reference device (cvi42).
Image from all MRI	All devices are derived and saved to MR DICOM Image file only. It is same point
DICOM Compliant networking	All devices are derived and saved to MR DICOM Image file only. It is same point.
Display of Images	All devices make to display clinical study and series related to cardiac MR DICOM Image. It is same point
Corresponding Tool	All devices control the contour tool for post-processing. It is same point.

2) Similar points between the subject device and the predicate device

Same Items	Description

Indication for use	Although specific indication for use is similar between the subject device and the predicate device including the reference device, all devices (subject device, predicate device and reference device) are intended to be used for viewing, post-processing and analysis of cardiac magnetic resonance (MR) images in a Digital Imaging and Communications in Medicine (DICOM) Standard format. It is same point.

3) Different points between the subject device and the predicate device

Same Items	Description
OS (Operating System)	The subject device is available with window O.S. However, predicated device and reference device are available with Mac OS, Microsoft including Window O.S. Although the OS (Operating System) is different between subject device and predicate device including reference device, Window O.S. is common O.S. under both devices. In addition, Software Validation of the subject device by utilizing Window O.S. had been conducted. Thus, this different point is not effected to safety and effectiveness of the subject device.
Store images	The subject device is intended to save the image file as the following file format name; dcm, json, csv, nii However, predicated device is intended to save the image file as following file format name; PDF, DML Although the file format name is different between subject device and predicate device including reference device, Software Validation of the subject device by utilizing the file format such as dcm, json, csb, nii, had been conducted. Thus, this different point is not effected to safety and effectiveness of the subject device.
Quantities assessment of cardiac function	The subject device is intended to analyze and assess the myocardiac data. However, predicated device and reference device are intended to analyze and assess the blood flow data including myocardiac data.

	Although the assessment data are different between subject device and predicate device including reference device, Software Validation for the analysis of the subject device, had been conducted. Thus, this different point is not effected to safety and effectiveness of the subject device.
Reports containing visualization of images and quantitative parameters	The subject device is intended to display the report containing T1, T2, T1 & T2 Mapping and LGE Data. However, predicated device and reference device are intended to display the report containing perfusion and flow analysis including T1, T2, T1 & T2 Mapping and LGE Data Although the display parameter is different between subject device and predicate device including reference device, Software Validation for displaying parameter of the subject device, had been conducted. Thus, this different point is not effected to safety and effectiveness of the subject device.

7. NON-CLINICAL DATA

7.1 Safety Test

The safety requirement is not required because it is stand-alone software.

7.2 Software

The following tests were performed to assess effectiveness of software of the device. The test was performed in accordance with following standards.

No.	Test Items	Standards
1	General requirement for safety – Programmable electrical medical systems (PEMS)	• IEC 62304:2006+A1:2015 • FDA Guidance ("Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices") • FDA Guidance ("Content of Premarket Submissions for Management of Cybersecurity in Medical Devices")

7.3 Performance Test

The following tests were performed to assess effectiveness of performance of the device to support equivalence between subject device and reference device related to predicate device. The test was performed in accordance with following standards.

Test ID	Test Item		Standard
SPPT001	Pre-requisite Verification		• This test checks whether Test Software (Myomics Q and cvi42) is installed on the appropriate system requirement (OS: window) So, To verify that the pre-requisite is completed for the execution of qualifi-cation
SPPT002	Import cardiac MR Images		• To verify that import function is working.
SPPT003	Export cardiac MR Images		• To verify that export MR images function is working.
SPPT004	Patient Data		• To verify that patient information function is working.
SPPT005	Series Overview		• To verify that series overview function is working properly.
SPPT006	Contour Drawing, Image Tools	Endocardium Contour	• To verify that contour drawing functions are working properly.
		Epicardium Contour	
		Move	
		Pinch	
		Nudge	
		Curved Line	
		Free Hand	

		Smoothing Undo Redo Restart Delete Confirm Zooming Panning Windowing	
SPPT007	T1 Analysis		• To verify that T1 analysis function is working properly. ※ T1 Analysis is just T1 Image or T1 Map, but is not the analysis function of T1 Map automatically.
SPPT008	T2 Analysis		• To verify that T2 analysis function is working properly. ※ T2 Analysis is just T2 Image or T2 Map, but is not the analysis function of T2 Map automatically.
SPPT009	LGE Analysis		• To verify that LGE analysis function is working properly. ※ LGE Analysis is just LGE Image, but is not the analysis function of LGE Image automatically.
SPPT010	Quantitative compare of polar map report in Native T1 analysis.		• To verify that the results of Myomics Q are very similar to the results of cvi42 in polar map report in Native T1 analysis. ※ The quantitative is depending on the user contour accuracy. So, few deviation could be happened until ±5% between both s/w
SPPT011	Quantitative compare of polar map report in Post T1 analysis.		• To verify that the results of Myomics Q are very similar to the results of cvi42 in polar map report in Post T1 analysis. ※ The quantitative is depending on the user contour accuracy. So, few deviation could be happened until ±5% between both s/w
SPPT012	Quantitative compare of polar map report in T2 analysis.		• To verify that the results of Myomics Q are very similar to the results of cvi42 in polar map report in T2 analysis ※ The quantitative is depending on the user contour accuracy. So, few deviation could be happened until ±5% between both s/w

7.4 Discussion

According to IEC 62304:2006+A1:2015 including “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” and ″Content of Premarket Submissions for Management of Cybersecurity in Medical Devices”, Software Validation applied of cybersecurity risk management is passed to ensure safety and performance for subject device (Myomics Q).

In addition, under bench test, control group is cvi42 because predicated device (cmr42) is end of production anymore. Although cvi42 is improved production from cmr42, cvi 42 includes same intended used and same function for Cardiac MR Image. So, cvi42 is control group because of reference product.

For the bench test between subject device (Myomics Q) and reference device (cvi42), both s/w demonstrate substantial equivalent of O.S. (Reference Test ID: SPPT001), DICOM Image Importing Function (Reference Test ID: SPPT002), DICOM Image Exporting Function (Reference Test ID: SPPT003), display of patient information (Reference Test ID: SPPT004), display of patient data (Cardiac MR Image; Series/Study Image) (Reference Test ID: SPPT005), contour control function (Reference Test ID: SPPT006) as a post-processing, display for T1 Map (Reference Test ID: SPPT007), for T2 Map (Reference Test ID: SPPT008) and for LGE Viewing (Reference Test ID: SPPT009),

Especially, both S/W are operated with almost quantitative evaluation Native T1 Map (Reference Test ID: SPPT010), Post T1 Map (Reference Test ID: SPPT011) and T2 Map (Reference Test ID: SPPT012) in the Polar Map. Quantitative evaluation are performed in cvi42 and Myomics Q for the analysis functions of Native T1 Map, Post T1 Map and T2 Map. The results of Myomics Q did not show a difference of more than ±5% compared to the results of cvi42 (95% of cvi42 results < Myomics Q Results < 105% of cvi42 results). Its deviation could be happened. The reason that the test result of Myomics Q and the result of cvi42 do not match 100% is because the value of the Polar Map Report may vary slightly depending on how the contour is drawn. It leads the result values are slightly different depending on how the contour is drawn, but the result is almost the same.

And, its data is just referenced to check image file, but it is not affected to directly clinical parameter for diagnostic justification of intended user. So, ±5% deviation data between subject device and reference device are not affected to clinical performance to achieve intended use.

According to above discussion, we claim the both S/W could be substantial equivalent.

8. CONCLUSION

Under the comparing substantial equivalence between the subject device and the predicate device including reference device, there are the same points such as general information, some technical and material information.

Although there is some deviation for comparing point between subject device and predicate device including reference device, the safety and performance test reports are supported to the safety and effectiveness by discussion of software validation and bench test.

In this regard, we conclude that the subject device is substantially equivalent to the predicate device.