



February 28, 2025

Phantomics Inc.  
Soeun Baek  
Manager  
152, Magokseo-ro, Gangseo-gu  
A-609  
Seoul, 07788  
Korea, South

Re: K241922  
Trade/Device Name: Myomics  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Medical image management and processing system  
Regulatory Class: Class II  
Product Code: QIH, LLZ  
Dated: January 21, 2025  
Received: January 21, 2025

Dear Soeun Baek:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

A handwritten signature in black ink, appearing to read "Samuel Park", is written over a large, light blue "FDA" watermark.

for

Jessica Lamb, Ph.D.

Assistant Director

Imaging Software Team

DHT8B: Division of Radiological Imaging

Devices and Electronic Products

OHT8: Office of Radiological Health

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K241922

Device Name

Myomics

### Indications for Use (Describe)

Myomics is intended to be used for viewing, post-processing, qualitative and quantitative evaluation of cardiovascular magnetic resonance (MR) images in a Digital Imaging and Communications in Medicine (DICOM) standard format. It enables a set of tools to assist physicians in qualitative assessment of cardiac images and quantitative measurements of the heart and adjacent vessels; and to view the presence or absence of physician-identified lesion in blood vessels.

The target population for manual workflows of Myomics is not restricted; however, semi-automated machine learning algorithms of Myomics are intended for an adult population.

The software comprises various analysis modules, including AI-powered algorithms, for a comprehensive evaluation of MR images.

Myomics is used for cardiac images acquired from a 3.0 T MR scanner.

Myomics shall be used only for cardiac images acquired from an MR scanner. 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.

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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K241922



The following 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Device Act 1990 and 21 CFR 807.92(c).

Date: May 21, 2024

**I. SUBMITTER**

- Submitter Name: Phantomics Inc.
- Address: A-609, 152, Magokseo-ro, Gangseo-gu, Seoul, Republic of Korea
- Data Prepared: May 21 2024
- Telephone Number: +82-10-5755-2840
- Contact Person: Soeun Baek
- Email: soeunbaek@phantomics.io

**II. DEVICE**

- Device's Trade Name: Myomics
- Device's Common Name: Automated Radiological Image Processing Software
- Regulation Number: 21CFR 892.2050
- Primary Product Code: QIH
- Secondary Product Code: LLZ
- 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)
- Classification Panel: Radiology

**III. PREDICATE DEVICE**

The primary predicate is Myomics Q (K211432) manufactured by Phantomics Inc. The cvi42 Auto Imaging Software Application (K213998), manufactured by Circle Cardiovascular Imaging Inc. is used as a secondary predicate device. The predicate devices have not been subject to design-related recall.

**IV. SUBJECT DEVICE DESCRIPTION**

Myomics is a software application for analysis cardiovascular MR images in 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 cardiovascular MR images qualitatively and quantitatively.

## V. INTENDED USE

Viewing, post-processing, qualitative and quantitative evaluation of blood vessels and cardiovascular MR images in DICOM format.

## VI. INDICATIONS FOR USE

The Indications for Use statement for the Myomics is not identical to the predicate device; however, the differences do not alter the intended use of the device, nor do they affect the safety and effectiveness of the device relative to the predicate.

**Table 1. Comparison to the predicate devices**

| -                  | <b>Subject Device</b><br><i>Myomics</i><br>Manufactured by Phantomics                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Primary Device</b><br><i>Myomics Q (K211432)</i><br>Manufactured by Phantomics                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Reference Device</b><br><i>cvi42 Auto (K213998)</i><br>Manufactured by Circle                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Indication for use | <p>Myomics is intended to be used for viewing, post-processing, qualitative and quantitative evaluation of cardiovascular magnetic resonance (MR) images in a Digital Imaging and Communications in Medicine (DICOM) standard format.</p> <p>It enables a set of tools to assist physicians in qualitative assessment of cardiac images and quantitative measurements of the heart and adjacent vessels; and to view the presence or absence of physician-identified lesion in blood vessels.</p> <p>The target population for manual workflows of Myomics is not restricted; however, semi-automated machine learning algorithms of Myomics are intended for an adult population.</p> <p>The software comprises various analysis modules, including AI-powered algorithms, for a comprehensive evaluation of MR images.</p> <p>Myomics is used for cardiac images acquired from a 3.0 T MR scanner.</p> | <p>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:</p> <ul style="list-style-type: none"> <li>- Importing cardiac MR images in DICOM format.</li> <li>- Supporting clinical diagnostics by analysis of cardiac MR images using display functionality such as panning, windowing, zooming through series/slices of the images.</li> <li>- Supporting clinical diagnostics analysis of the heart in cardiac MR images and signal intensity.</li> <li>- Software package is designed to support the physician-to-physician compliance assessment, document and follow up heart disease by cardiac MRI.</li> </ul> <p>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.</p> | <p>cvi42 Auto is intended to be used for viewing, post-processing, qualitative and quantitative evaluation of cardiovascular magnetic resonance (MR) and computed tomography (CT) images in a Digital Imaging and Communications in Medicine (DICOM) Standard format.</p> <p>It enables a set of tools to assist physicians in qualitative assessment of cardiac images and quantitative measurements of the heart and adjacent vessels; perform calcium scoring; and to confirm the presence or absence of physician-identified lesion in blood vessels.</p> <p>The target population for cvi42 Auto's manual workflows is not restricted; however, cvi42 Auto's semi-automated machine learning algorithms are intended for an adult population.</p> <p>cvi42 Auto shall be used only for cardiac images acquired from an MR or CT scanner. It shall be used by qualified medical professionals, experienced in examining and evaluating cardiovascular MR or CT images,</p> |

## Myomics 510(k) SUMMARY



| - | <b>Subject Device</b><br><i>Myomics</i><br>Manufactured by Phantomics                                                                                                                                                                                                                                                | <b>Primary Device</b><br><i>Myomics Q (K211432)</i><br>Manufactured by Phantomics                                                                                                | <b>Reference Device</b><br><i>cvi42 Auto (K213998)</i><br>Manufactured by Circle                                   |
|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|
|   | Myomics shall be used only for cardiac images acquired from an MR scanner. 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. | 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. | for the purpose of obtaining diagnostic information as part of a comprehensive diagnostic decision-making process. |

## VII. SUBSTANTIAL EQUIVALENCE

**Table 2. General comparison to the predicate devices**

| -                 | Subject Device                             | Primary Device                             | Reference Device                           |
|-------------------|--------------------------------------------|--------------------------------------------|--------------------------------------------|
| Device Name       | Myomics                                    | Myomics Q                                  | cvi42 Auto Imaging Software Application    |
| 510(k) Number     | -                                          | K211432                                    | K213998                                    |
| Manufacturer      | Phantomics Inc.                            | Phantomics Inc.                            | Circle Cardiovascular Imaging Inc.         |
| Regulation Number | 21CFR892.2050                              | 21CFR892.2050                              | 21CFR892.2050                              |
| Regulation Name   | Picture Archiving and Communication System | Picture Archiving and Communication System | Picture Archiving and Communication System |
| Classification    | Class II                                   | Class II                                   | Class II                                   |
| Product Code      | QIH                                        | LLZ                                        | QIH                                        |

**Table 3. Feature comparison table of Myomics with the predicate devices**

| -                                           | <b>Subject Device</b><br><i>Myomics</i><br>Manufactured by Phantomics                                                                  | <b>Primary Device</b><br><i>Myomics Q (K211432)</i><br>Manufactured by Phantomics | <b>Reference Device</b><br><i>cvi42 Auto (K213998)</i><br>Manufactured by Circle                                                                |
|---------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|
| Imaging Modalities                          | MR                                                                                                                                     | MR                                                                                | MR and CT                                                                                                                                       |
| Imaging Type                                | Cardiovascular                                                                                                                         | Cardiovascular                                                                    | Cardiovascular                                                                                                                                  |
| DICOM Compliant Networking                  | Yes                                                                                                                                    | Yes                                                                               | Yes                                                                                                                                             |
| Import and Display MR images                | Yes                                                                                                                                    | Yes                                                                               | Yes                                                                                                                                             |
| Images can be displayed by study and series | Yes                                                                                                                                    | Yes                                                                               | Yes                                                                                                                                             |
| Segmentation of regions of interest         | Yes (Endocardium and epicardium contour segmentation)                                                                                  | Yes (Endocardium and epicardium contour segmentation)                             | Yes (Endocardium and epicardium contour segmentation)                                                                                           |
| Store images                                | Yes (File Format: dcm, json, nii, csv)                                                                                                 | Yes (File Format: dcm, json, nii, csv)                                            | Yes (File Format: PDF, XML)                                                                                                                     |
| Machine Learning Based Algorithm            | Yes (Semi-automatic segmentation)                                                                                                      | No                                                                                | Yes (Semi-automatic segmentation)                                                                                                               |
| Quantitative Assessment of Cardiac Function | Yes (Manual segmentation, and semi-automatic segmentation using Machine Learning technique of four heart chambers in short-axis views) | Yes (Manual segmentation)                                                         | Yes (Manual segmentation, and semi-automatic segmentation using Machine Learning technique of four heart chambers in long and short-axis views) |
| Operating System                            | Microsoft Windows                                                                                                                      | Microsoft Windows                                                                 | Mac OS and Microsoft Windows                                                                                                                    |
| Software Development Standard               | IEC 62304:2006+A1:2015                                                                                                                 | IEC 62304:2006+A1:2015                                                            | IEC 62304:2006+A1:2015                                                                                                                          |
| Risk Management Standard                    | ISO 14971:2019                                                                                                                         | ISO 14971:2007                                                                    | ISO 14971:2019                                                                                                                                  |

## VIII. PERFORMANCE DATA AND TESTING

### 1) Performance Test

A bench performance test was conducted to verify the substantial equivalence in performance between the subject device (Myomics) and the predicate device (Myomics Q). These devices analyze cardiovascular MR images and have general worklist functions such as importing, displaying, exporting images, manually drawing contours, and reporting. It was also conducted to compare the semi-automatic segmentation function (endocardium and epicardium contour) between the subject device (Myomics) and the secondary predicate device (cvi42 auto). The bench performance test confirmed the substantial equivalence of the subject device (Myomics) to both predicate devices (cvi42 auto and Myomics Q).

### 2) Verification and validation

Software verification and validation of Subject device (Myomics) has been tested according to “ISO 13485:2016”, “IEC 62304:2015” and “ISO 14971:2019”.and all documents have been made according to the Software Development Plan of Myomics.

### 3) Validation of AI Modules

The machine learning algorithms of Myomics were trained and tested using images from various major MR imaging device vendors. The data used for AI performance testing was not utilized during the algorithm training process. The training involved a dataset of 3723 anonymized cases, separate from the test set. This dataset was divided into training, validation, and test sets at a ratio of 80%, 10%, and 10% respectively, yielding 3723 cases for training and 378 cases each for validation and AI performance testing.

The AI performance testing dataset originally contained 378 test cases. To improve generalizability and evaluate performance across different MRI manufacturers, 50 additional cases were included per AI module, increasing the total number of test cases from 378 to 728.

**Table 4. AI Module Description in Myomics**

| AI Module No. | Data Group (AI Model Name)            | Training   | Validation | Test      |
|---------------|---------------------------------------|------------|------------|-----------|
| AIM-01        | Native T1 Map Myocardium Segmentation | 594 cases  | 42 cases   | 92 cases  |
| AIM-02        | Post T1 Map Myocardium Segmentation   | 498 cases  | 41 cases   | 91 cases  |
| AIM-03        | T2 Map Myocardium Segmentation        | 586 cases  | 59 cases   | 109 cases |
| AIM-04        | CINE Myocardium Segmentation          | 640 cases  | 40 cases   | 90 cases  |
| AIM-05        | LGE PSIR Myocardium Segmentation      | 491 cases  | 27 cases   | 77 cases  |
| AIM-06        | CINE RV Myocardium Segmentation       | 437 cases  | 142 cases  | 192 cases |
| AIM-07        | LGE Magnitude Myocardium Segmentation | 477 cases  | 27 cases   | 77 cases  |
| SUM           |                                       | 3723 cases | 378 cases  | 728 cases |

Across all MR machine manufacturers n= 728 anonymized patient images were used for the AI performance test of Myomics. This translates into 92 cases for Native T1 Map Myocardium Segmentation, 91 cases for Post T1 Map Myocardium Segmentation, 109 cases for T2 Map Myocardium Segmentation, 90 cases for CINE Map Myocardium Segmentation, 77 cases for LGE PSIR Myocardium Segmentation, 192 cases for CINE RV Myocardium Segmentation, and 77 cases for LGE Magnitude Myocardium Segmentation. All AI performance testing results met pre-defined acceptance criteria in Phantomics.

The AI performance acceptance criteria, defined using the DICE Score, were applied to evaluate the ML model's effectiveness in segmenting the Myocardium. The DICE Score is a common metric used in computer vision and medical imaging to measure the similarity or overlap between two sets. It is typically used in image segmentation and object detection. Upon evaluating the performance of each AI module used in Myomics, all modules attained an average DICE Score of over 0.7. All data and results from the AI performance test have been documented in accordance with quality system of Phantomics.

### **IX. CONCLUSION**

In comparing substantial equivalence between the subject device and the predicate device, similarities are found in general, technical and material information. Despite some differences, the safety and performance test reports affirm the safety and effectiveness of the subject device. Therefore, we conclude that the subject device is substantially equivalent to the predicate device. The information provided in this premarket notification, which includes performance testing and comparisons with the predicate devices, attests to the safety and effectiveness of Myomics for its intended use.