Ultromics Limited
% Jaco Jacobs
Chief Regulatory and Compliance Officer
4630 Kingsgate, Cascade Way
Oxford Business Park South
Oxford, Oxfordshire OX4 2SU
UNITED KINGDOM

December 20, 2021

Re: K213275
Trade/Device Name: EchoGo Core (2.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: September 27, 2021
Received: September 30, 2021

Dear Jaco Jacobs:

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 and Part 809); 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.*

Submission Number *(if known)*

K213275

Device Name

EchoGo Core (2.0)

Indications for Use *(Describe)*

EchoGo Core is intended to be used for quantification and reporting of results of cardiovascular function to support physician diagnosis. EchoGo Core is indicated for use in adult populations.

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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# K213275

510(K) SUMMARY

# 1 Submitter

| | |
|---|---|
| Company | Ultromics Limited<br>4630 Kingsgate Cascade Way, Oxford Business Park South, Oxford, Oxfordshire, United Kingdom, OX4 2SU |
| Contact | Dr. Jaco Jacobs |
| Date Prepared | 27 November 2021 |

# 2 Subject Device

| | |
|---|---|
| Product Trade Name | EchoGo Core |
| Model Number | 2.0 |
| Medical Speciality | Radiology |
| Regulation | 892.2050 – Picture Archiving and Communications System |
| Product Code | QIH – Automated Radiological Image Processing Software |
| Regulatory Class | II |

EchoGo Core is the *product trade name* and 2.0 is the *model number*. For the avoidance of doubt, in this submission we combine the product trade name and model number and refer to the subject device as EchoGo Core 2.0.

# 3 Predicate and Reference Devices

| | |
|---|---|
| Predicate Device | EchoGo Core |
| 510(k) | K191171 |
| Manufacturer | Ultromics Limited |

| | |
|---|---|
| Reference Device | TomTec Arena TTA2 |
| 510(k) | K150122 |
| Manufacturer | TomTec Imaging Systems GmbH |

# 4 Device Description

EchoGo Core 2.0 is a software application manufactured by Ultromics to provide a report of left ventricular cardiac function, in the form of secondary capture DICOM files and/or as a structured DICOM report, to aid interpreting physicians with diagnostic decision-making process. EchoGo Core 2.0 applies to ultrasound images of the heart (echocardiograms).

EchoGo Core 2.0 utilizes artificial intelligence (AI) for the operator-assisted automatic quantification of commonly measured echocardiographic metrics[1]. Independent training, test and validation datasets were used for training and performance assessment of the device.

EchoGo Core 2.0 requires an operator at key steps to confirm or relabel automatically labeled acquisition views (if required) and approve the left ventricle segmentations (contours) proposed by the AI.

EchoGo Core 2.0 operates in a sequential workflow manner, that includes:

1. Automatic view classification and labeling
2. Operator confirmation or relabeling of view classifications
3. Contouring of the left ventricle in apical chamber views
4. Automated heart cycle identification and end-diastolic and end-systolic frame selection
5. Operator confirmation or rejection of left ventricle contouring and frame selection
6. Calculation of clinical report metrics

To identify a heart cycle, the heart rate must be known. If an ECG was not taken during acquisition of the echocardiogram, the heart rate may be inferred. The operator is supported in selecting a contoured image clip for each view and approving the selected cycle (and the key end-diastolic (ED) and end-systolic (ES) frames). The operator will review the report produced and may be asked to approve cautions that are added to the report. EchoGo Core 2.0 supports the production of reports for any combination of the three processible views (A2C, A3C and A4C), either embedded as image files in one or more multi-frame true color secondary capture DICOM files, and/or as a DICOM structured report.

# 5 Indications for Use

EchoGo Core 2.0 is intended to be used for quantification and reporting of results of cardiovascular function to support physician diagnosis. EchoGo Core 2.0 is indicated for use in adult populations.

Both the intended use and indications for use statement for the subject and predicate devices are identical. Both the subject and predicate devices are indicated for use in quantification and reporting of cardiovascular function to support the physician's diagnosis in an adult population.

# 6 Comparison of Technological Characteristics

A comparison of technological differences between the subject and predicate devices follows.

| Characteristic | Subject Device<br>EchoGo Core 2.0 | Predicate Device<br>EchoGo Core 1.0 |
|---|---|---|
| Intended use | Identical | Quantification of cardiovascular function from an echocardiogram |
| Indications for use | Identical | Quantification and reporting of results of cardiovascular function to support physician diagnosis. EchoGo Core is indicated for use in adult populations |
| Anatomical site | Identical | Cardiovascular structures |
| Users | Identical | Accredited echocardiographers and sonographers at Ultromics |
| Machine learning-based algorithm | Yes | Yes |
| Algorithms | • Auto-Contouring<br>• DICOM Handling | • Auto-Contouring<br>• DICOM Handling |

| Characteristic | Subject Device<br>EchoGo Core 2.0 | Predicate Device<br>EchoGo Core 1.0 |
|---|---|---|
| | • Technical QC<br>• Auto-View Classification<br>• Manual Labelling UI<br>• Contour Selection and Approval<br>• Metrics Calculation<br>• Auditing<br>• Service Webhooks<br>• Reporting | • Technical QC<br>• Manual Labelling UI<br>• Contour Selection and Approval<br>• Metrics Calculation<br>• Auditing<br>• Reporting |
| Operates on DICOM clips | Yes | Yes |
| Average GLS A2C/A4C views | Yes | Yes |
| Average GLS A2C/A4C/A3C views | Yes | No |
| Per view GLS, EF and LV volume | Yes | No |
| Segmental LS | Yes | No |
| Echocardiogram images on device report | Yes | Yes |
| Horseshoe and bullseye representations | Yes | No |
| Mechanical dispersion plot | Yes | No |
| Strain temporal intensity plot/CAMM plot | Yes | No |
| Contours overlayed on echocardiogram images | Yes | No |
| Auto-view classification | Yes | No |
| Automatic ED/ES frame detection | Yes | Yes |
| EF Reported | Yes | Yes |
| Automated EF calculation | Yes | Yes |
| Simpson's biplane LV volume calculation | Yes | Yes |
| Non-Simpson's bi-plane LV volume calculation methods | Yes | No |
| LV ED/ES volume indexed values | Yes | No |
| EF results shown with video clip | Yes | Yes |
| User confirmation / rejection of result | Yes | Yes |
| Manual editing of automated result by user | No | No |
| LV stroke volume | Yes | No |
| LV length | Yes | No |
| Operating system | Windows | Windows |
| Operating platform | Single software application platform | Single software application platform |
| Software | Complies with IEC 62304:2015 and developed under an FDA QSR | Complies with IEC 62304:2006 and developed under an FDA QSR |

| Characteristic | Subject Device<br>EchoGo Core 2.0 | Predicate Device<br>EchoGo Core 1.0 |
|---|---|---|
| | compliant QMS incorporating risk management per ISO 14971:2019 | compliant QMS incorporating risk management per ISO 14971:2007 |
| **Usability** | Complies with IEC 62366-1:2020 and general use of FDA guidance on usability engineering | General use of FDA guidance on usability engineering |
| **Performance testing** | Equivalent to reference comparator TomTec Arena TTA2 (K150122) | Equivalent to reference comparator TomTec Arena TTA2 (K150122) |

Both the subject and predicate devices have similar technological characteristics and principles of operation. Any technological differences between the subject and predicate devices raise no new concerns with regards to safety and efficacy.

# 7 Consensus Standards

The following consensus standards were used in the design and manufacture of EchoGo Core 2.0.

| Standard | Recognition Number |
|---|---|
| ISO 14971:2019 – Medical Devices – Application of Risk Management to Medical Devices | 5-125 |
| IEC 62304:2015 – Medical Device Software – Software Life Cycle Processes | 13-79 |
| IEC 62366-1:2020 – Medical Devices – Application of Usability Engineering to Medical Devices | 5-129 |
| NEMA PS 3.1 – PS 3.20 (2016) – Digital Imaging and Communications in Medicine (DICOM) Set | 12-300 |
| IEC ISO 10918-1:1994 – Digital Compression and Coding of Continuous-tone Still Images | 12-261 |

Ultromics Limited cites conformity to the voluntary standards above. In addition, EchoGo Core 2.0 was designed and manufactured under a QMS that fully conforms to ISO 13485:2016.

# 8 Performance Data

## 8.1 Software Verification and Validation

EchoGo Core software was developed and tested in accordance with Ultromics' Design Control processes and has been subjected to extensive safety and performance testing. Non-clinical verification and validation test results established that the device meets its design requirements and intended use. Specifically, software verification was conducted at unit, module, and system integration levels. Risk management analysis generated multiple risk mitigation measures and verification activities. Formative and summative usability assessments were conducted during formal development. Cybersecurity and data security testing were conducted to verify that data and patient protected health information security measures are included in the design of the software.

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*. The software for this device is considered as a moderate level of concern, since a failure or latent design flaw could indirectly result in minor injury to the patient through incorrect or delayed information or through the action of a care provider.

EchoGo Core 2.0 passed all software verification and validation tests.

## 8.2 Essential Performance

Performance testing was conducted to demonstrate substantial equivalence to the predicate device, EchoGo Core 1.0, via a reference comparator device, TomTec Arena TTA2. Pre-determined acceptance criteria were formalised in terms of Root Mean Square (RMS) error against reference values generated using the comparator device, for each reported metric. The acceptance criteria were formalised such that EchoGo Core 2.0 would produce measures of left ventricular (LV) length, volume at end diastole (ED) and end systole (ES), ejection fraction (EF), stroke volume, cardiac output, global longitudinal strain (GLS) and segmental longitudinal strain (SLS) with an RMS error below a set, pre-determined threshold.

A formal retrospective, non-interventional validation study was conducted using 214 previously *unseen* studies. Left ventricle volume and metrics subsequently derived, such as ejection fraction, were calculated. For global longitudinal strain and segmental strain at peak and end-systole, LV contour Euclidean distances were calculated. The performance dataset used was representative of the intended patient population over a clinically representative range of measures. The population was gender-balanced over clinically typical age, weight, and height ranges. Performance testing included acquisitions from multiple ultrasound system manufacturers to validate essential performance across multiple scanner platforms and settings. Test datasets were strictly segregated from algorithm training datasets. Root mean square error was calculated as the primary endpoint. The primary endpoint was met. Performance against the comparator device is summarised as follows.

| Left Ventricular Metric | % Root Mean Square Error |
|---|---|
| Length | 3.06 – 4.59 |
| Volume at End Diastole and End Systole | 8.57 – 16.59 |
| Ejection Fraction | 6.69 – 8.50 |
| Stroke Volume | 10.57 – 13.68 |
| Global Longitudinal Strain | 3.36 – 4.79 |
| Systolic Segmental Longitudinal Strain | 5.51 – 9.98 |

Three operators processed a total of 214 TTE studies, respectively. Inter-operator variability demonstrated acceptable performance with a Deming RMSE of 0 for all report metrics. Similarly, intra-operator variability demonstrated acceptable performance with a Deming RMSE of 0 for all report metrics. The repeatability results for EchoGo Core 2.0 demonstrated acceptable performance.

All measurements produced by EchoGo Core 2.0 were deemed to be substantively equivalent to the predicate device and met acceptable levels of performance. We therefore consider EchoGo Core 2.0 to be substantively equivalent to the predicate device and is therefore deemed to be safe and effective.

# 9 Conclusions

The subject device, EchoGo Core 2.0 is as safe and as effective as the predicate device, EchoGo Core 1.0, previously cleared under K191171. The subject and predicate devices have identical intended uses and indications for use, and similar technological characteristics and principles of operation. Any minor differences raise no new concerns with regards to safety and effectiveness. Essential performance of both the subject and predicate devices were evaluated against a comparator reference device, TomTec Arena TTA2, previously

cleared under K150122. Performance data demonstrate that EchoGo Core 2.0 and EchoGo Core 1.0 have similar essential performance.

It follows that EchoGo Core 2.0 is substantially equivalent to EchoGo Core 1.0.