Ultromics Ltd.
% Ms. Melissa Clark
Head of Regulatory
Stansfeld Park, Quarry Road
Oxford Oxfordshire OX3 8SB
ENGLAND

November 13, 2019

Re: K191171
Trade/Device Name: EchoGo Core
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: QIH
Dated: October 16, 2019
Received: October 18, 2019

Dear Ms. Clark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191171

Device Name
EchoGo Core

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.

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510(k) SUMMARY
Ultromics Ltd. K191171
EchoGo Core

1. Submitter

Company & Address: Ultromics Ltd.
Stansfeld Park
Quarry Road
OX3 8SB
UK
Contact Person: Melissa Clark
Phone: +44 7557 650 514

Date Prepared: October 16, 2019

2. Device

Name of Device: EchoGo Core
Common or Usual Name: Automated Radiological Image Processing System
Classification Name: Picture archiving and communications system
Regulatory Class: II
Product Code: QIH

3. Predicate Devices

Device	510(k) Number	Device Name	Manufacturer
Predicate Device	K150122	TomTec Arena TTA2	TomTec Imaging Systems, GmbH
Reference Device	K173780	EchoMD Automated Ejection Fraction Software	Bay Labs, Inc.

Neither the predicate nor reference device has been subject to a design-related recall.

4. Device Description

EchoGo Core is a standalone software application that automatically measures standard cardiac parameters including Ejection Fraction (EF), Global Longitudinal Strain (GLS), and Left Ventricular (LV) volume. EchoGo Core provides a service to calculate those values and provide a report back to the clinician.

EchoGo Core analyzes echocardiogram cardiac parameters. An echocardiogram is performed using standard echocardiograms protocols. The anonymized echocardiogram dataset is transferred to Ultromics and once received the images are processed through the application's workflow.

Once the technical QC has been performed, the automated contour detection of the endocardium of the LV is reviewed and approved by trained operators. Identifying and outlining the LV is standard practice in echocardiography and present in many other cleared devices, including the predicate device TomTec Arena TTA2 (K150122). In the proposed device, an auto-contouring algorithm places points around the LV that sufficiently capture the LV shape. These contours are used in calculations for geometric parameters.

As with the TomTec Arena TTA2, the following parameters are calculated for inclusion in the report:

- EF: calculated from Simpson's Biplane Method (SBM) LV Volumes
- GLS_{AVG}: standard calculations, averaged from 2 chamber and 4 chamber views
- LV volume: SBM calculated left ventricular volumes

A worksheet is automatically generated from the calculated parameters which is returned to the interpreting clinician. This report is intended as an additional input to standard diagnostic pathways and is only to be used by qualified clinicians.

5. Indications for Use

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.

The Indications for Use statement for the EchoGo Core is virtually identical to the predicate device. Minor differences between the subject and predicate indications for use do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices are indicated for use in quantification and reporting of cardiovascular function to support the physician's diagnosis; the only difference is that the predicate device is also used in quantification and reporting of fetal and abdominal function.

The EchoGo Core and the predicate are identical with regard to intended use; specifically, quantification of cardiovascular function from an echocardiogram.

6. Comparison of Technological Characteristics with the Predicate Device

Quantification and reporting of results of cardiovascular function is the technological principle for both the subject and predicate devices, specifically EF, GLS, and LV volume. The results of quantification of cardiovascular function are used as an aid to diagnosis. At a high level, the subject and predicate devices are based on the following same technological elements:

- Quantification of cardiovascular function based on the analysis of echocardiogram data
- Identifying and outlining the LV
- Auto-contouring of the LV
- Reporting of EF using Simpson's biplane method (SBM)

- Reporting of GLS using standard calculations
- Reporting of LV volumes using SBM

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

- EchoGo Core uses machine learning-based algorithms.
  - Note: The reference device, EchoMD Automated Ejection Fraction Software, has the same intended use as EchoGo Core and provides machine learning-based algorithms for automated estimates of EF.
- TomTec Arena TTA2 provides additional offerings for the convenience of the user including fetal and abdominal functions, and additional cardiac functions.
- EchoGo Core does not allow for manual editing of contours whereas the predicate, TomTec allows for manual editing. A quality control procedure applied to input image data ensures the device output is consistent with the accuracy and reproducibility demonstrated through performance testing.

  The results of the performance testing indicated that by not allowing for manual editing in the EchoGo Core device inter and intra-operator variability (0% bias and RMSE) was eliminated, while inter and intra-operator variability remained for the predicate, TomTec Arena TTA2 (5.3-12.0% and 2.5-4.7% RMSE for EF and GLS, respectively). Furthermore, during performance testing, a user was given the opportunity to review the predicate's automatically generated contour and subsequently perform a decisive action, that being to accept the contour unchanged, or manually adjusts the contour to become acceptable to the user. Similarly, the user was given the opportunity to review the EchoGo Core automatically generated contour and subsequently perform a decisive action, that being to accept the contour unchanged, or reject the contour completely. This was included in performance testing as a study rejection due to "poor contour tracking" for EchoGo Core. Results using 5 Operators showed that manual contour editing was required in uo to 100% of cases processed through the predicate, while contour rejection was required in up to 29% of cases processed through EchoGo Core. Thus, in this aspect, it is considered that the automated contouring element of EchoGo Core is substantively equivalent to TomTec Arena TTA2.

7. Performance Data

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "*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 or operator through incorrect or delayed information or through the action of a care provider.

Performance Testing

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. A 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.

Verification and validation testing were conducted to demonstrate substantial equivalence to TomTec Arena TTA2. The success criterion was that EchoGo Core would produce an ejection fraction, global longitudinal strain, end-systolic volume and end-diastolic volume with a Root Mean Square Error below a set threshold, as compared to the reference values generated using TomTec Arena TTA2.

A formal retrospective, non-interventional validation study was conducted using 378 previously acquired studies. Left ventricle volumes and subsequent ejection fraction was calculated using the Simpson's biplane method. For global longitudinal strain end-diastole and end-systole contour lengths were calculated. The patient dataset was constructed to provide a representative range of volume, ejection fraction and global longitudinal strain values, in a patient population with a balanced gender proportion and clinically typical age, weight and height ranges. Testing included a wide array of ultrasound system manufacturers to verify that EchoGo Core performs acceptably across multiple scanner platforms. Variability testing was also performed to demonstrate that EchoGo Core performs acceptably with a variety of image clips and frames from the same patient. Test datasets were strictly segregated from algorithm training datasets. EchoGo Core volume, ejection fraction and global longitudinal strain measurements were produced by a range of users (echocardiographers and cardiologists) and compared to values produced using TomTec Arena TTA2 by a range of users (echocardiographers and cardiologists). Root mean square error was calculated as the primary endpoint. The primary endpoint was met (results: 5.02%, 2.89%, 8.0 ml and 11.1 ml RMSE, for ejection fraction, global longitudinal strain, end-diastolic and end-systolic volumes, respectively). Inter and intra-operator variability was assessed between operators processing the same images and in all cases no variation was observed. Based on the clinical performance as documented in this pivotal clinical study, the device has a safety and effectiveness profile that is equivalent to the predicate TomTec Arena TTA2.

8. Conclusions

The EchoGo Core is as safe and effective as the TomTec Arena TTA2. The EchoGo Core has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the EchoGo Core and its predicate devices raise no

new issues of safety or effectiveness. Performance data, including software verification and validation and performance testing demonstrate that the EchoGo Core is as safe and effective as the TomTec Arena TTA2. Thus, the EchoGo Core is substantially equivalent.