November 23, 2022

Ultromics Limited
Jaco Jacobs
Chief Regulatory and Compliance Officer
4630 Kingsgate
Cascade Way, Oxford Business Park
Oxford, OX4 2SU
United Kingdom

Re: K222463
Trade/Device Name: EchoGo Heart Failure
Regulation Number: 21 CFR 870.2200
Regulation Name: Adjunctive Cardiovascular Status Indicator
Regulatory Class: Class II
Product Code: QUO
Dated: October 24, 2022
Received: October 25, 2022

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); 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,

Stephen C. Browning -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
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)*
K222463

Device Name
EchoGo Heart Failure

Indications for Use *(Describe)*
EchoGo Heart Failure 1.0 is an automated machine learning-based decision support system, indicated as a diagnostic aid for patients undergoing routine functional cardiovascular assessment using echocardiography. When utilised by an interpreting clinician, this device provides information that may be useful in detecting heart failure with preserved ejection fraction (HFpEF).

EchoGo Heart Failure 1.0 is indicated in adult populations over 25 years of age. Patient management decisions should not be made solely on the results of the EchoGo Heart Failure 1.0 analysis.

EchoGo Heart Failure 1.0 takes as input an apical 4-chamber view of the heart that has been captured and assessed to have an ejection fraction ≥50%.

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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1 Submitter

Company	Ultromics Limited 4630 Kingsgate Cascade Way, Oxford Business Park South, Oxford, Oxfordshire, United Kingdom, OX4 2SU
Contact	Dr. Jaco Jacobs
Date Prepared	18th November 2022

2 Subject Device

Product Trade Name	EchoGo Heart Failure
Model Number	1.0
510(k)	K222463
Manufacturer	Ultromics Limited
Medical Speciality	Cardiology
Regulation	21 CFR 870.2200 – Adjunctive Cardiovascular Status Indicator
Product Code	QUO – Adjunctive Heart Failure Status Indicator
Regulatory Class	II

EchoGo Heart Failure is the *product trade name* and 1.0 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 Heart Failure 1.0.

3 Predicate Device

Predicate Device	T3 Platform Software
510(k)	K213230
Manufacturer	Etiometry Inc.

4 Device Description

EchoGo Heart Failure 1.0 is a software-only medical device manufactured by Ultromics Limited and granted breakthrough status by the FDA under Q212613.

EchoGo Heart Failure 1.0 takes as input a DICOM file containing an echocardiogram and reports a classification decision suggestive of the presence or absence of heart failure with preserved ejection fraction (HFpEF). The output of this device is based on an artificial intelligence (AI) model developed using a convolutional neural network that produces the classification result. The model takes as input a 2D echocardiogram in which an apical 4-chamber view of the heart has been captured and assessed to have an ejection fraction ≥50% (this would normally be computed using a medical device for the assessment of cardiac function of the left

ventricle, for example K213275). The echocardiogram should be acquired without contrast and contain at least one full cardiac cycle.

Independent training, validation and test datasets were used for training and performance assessment of the device. EchoGo Heart Failure 1.0 is fully automated and does not comprise a user interface.

EchoGo Heart Failure 1.0 produces a report containing the result of the classification, and this report is intended to be used by an interpreting clinician as an aid to diagnosis for HFpEF. The results are intended as an additional input to standard diagnostic pathways and should only be used by an interpreting clinician. The device is a diagnostic aid and thus according to common medical sense and the principles of differential diagnosis any diagnostic finding derived from usage of this product must be confirmed by additional diagnostic investigations, if in doubt. The ultimate diagnostic decision remains the responsibility of the interpreting clinician using patient presentation, medical history, and the results of available diagnostic tests, one of which may be EchoGo Heart Failure 1.0.

EchoGo Heart Failure 1.0 is a prescription only device.

5 Context

5.1 Intended Use

Providing adjunctive information on a patient's cardiovascular condition (diagnostic aid for Heart Failure with Preserved Ejection Fraction (HFpEF)).

5.2 Intended User

The clinician interpreting the report produced by EchoGo Heart Failure 1.0 and making a diagnostic decision.

5.3 Indications for Use

EchoGo Heart Failure 1.0 is an automated machine learning-based decision support system, indicated as a diagnostic aid for patients undergoing routine functional cardiovascular assessment using echocardiography. When utilised by an interpreting clinician, this device provides information that may be useful in detecting heart failure with preserved ejection fraction (HFpEF).

EchoGo Heart Failure 1.0 is indicated in adult populations over 25 years of age. Patient management decisions should not be made solely on the results of the EchoGo Heart Failure 1.0 analysis.

EchoGo Heart Failure 1.0 takes as input an apical 4-chamber view of the heart that has been captured and assessed to have an ejection fraction ≥50%.

5.4 Patient Population

Patients undergoing routine functional cardiovascular assessment using diagnostic echocardiography or those suspected of heart failure.

6 Comparison of Intended Use

Both the subject and predicate devices are software-only devices as the subject device is an "automated machine learning based decision support system" and the predicate device "features the T3 Data Aggregation & Visualization software module version 5.0 and the T3 Risk Analytics Engine software module version 8.0".

Both devices are indicated as adjunctive devices that provide information that may be useful for healthcare professionals in forming a diagnostic decision. The subject device is a "diagnostic aid for patients undergoing routine functional cardiovascular assessment" and the predicate device is intended to be used "to utilize this information to aid in clinical decisions".

Both devices are intended to provide information on the cardiovascular state of patients. The subject device "provides information that may be useful in detecting heart failure with preserved ejection fraction (HFpEF)", whereas the predicate device "presents partial quantitative information about the patient's cardiovascular condition".

Both the subject and predicate devices are adjunctive devices and patient management decisions should not be made solely on device recommendations. Specifically, for the subject device "Patient management decisions should not be made solely on the results of the EchoGo Heart Failure 1.0 analysis"; the predicate states that "The primary data should be reviewed as part of standard patient evaluations and no decisions should be solely based on the indices".

Both the subject and predicate devices have indications for adult populations. The subject device "EchoGo Heart Failure 1.0 is indicated in adult populations over 25 years of age" and the predicate is indicated for use on "adult, paediatric, and neonatal patients".

For purposes of substantial equivalence, the term intended use means the general purpose of the device or its function and encompasses the indications for use. The term indications for use describes the disease the device is intended to serve as a diagnostic aid including a description of the patient population for which the device is intended. Both devices are intended as adjunctive aids for cardiovascular states or conditions and both devices can be used on adult populations. It follows that both devices have the same intended use of providing adjunctive information on the cardiovascular condition of a patient.

Any minor differences between the intended use and/or indications for use do not raise any new concerns with regards to safety and effectiveness. The regulation product code of the predicate device, PPW, under the associated regulation includes special controls that were applied to the subject device. The general controls and special controls of the predicate device are sufficient to ensure the substantial equivalence of the subject device and adequately control any differences.

7 Comparison of Technological Characteristics

A full comparison of the technological characteristics of the subject and predicate devices follows.

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

- The subject device takes as input a DICOM file containing an echocardiogram and the predicate device uses as input numeric physiological information from medical devices to which it is connected. Both devices therefore receive as input data that is the output of another medical device.
- The output of the subject device is based on an artificial intelligence (AI) model developed using a convolutional neural network that produces a classification result. The output of the predicate device is derived from mathematical manipulations of physiologic data and measurements received from connected devices.
- The subject device reports a classification decision as suggestive or not suggestive of the presence of heart failure with preserved ejection fraction (HFpEF), while the predicate device calculates indices that provides information on the respiratory or cardiovascular status of patients (IVCO2 and ACD, HLA and IDO2, respectively). Both devices are adjunctive cardiovascular status indicators.
- The predicate device outputs or displays amalgamated information from connected devices not output by the subject device, for example:
  - Airway flow, volume, and pressure
  - Arterial blood pressure (invasive and non-invasive, systolic, diastolic, and mean)
  - Bi-spectral index (BIS, signal quality index, suppression ratio)
  - Cardiac Index
  - Cardiac output
  - Central venous pressure
  - Cerebral perfusion pressure
  - End-tidal CO2
  - Heart rate
  - Heart rate variability
  - Intracranial pressure
  - Left atrium pressure
  - Oxygen saturation (intravascular, regional, SpO2)
  - Premature ventricular counted beats
  - Pulmonary artery pressure (systolic, diastolic, and mean)
  - Pulse pressure variation
  - Pulse Rate
  - Respiratory rate
  - Right atrium pressure
  - Temperature (rectal, oesophageal, tympanic, blood, core, nasopharyngeal, skin)
  - Umbilical arterial pressure (systolic, diastolic, and mean)

The following table summarises technological characteristics.

Characteristic	Subject Device EchoGo Heart Failure 1.0	Predicate Device T3 Platform Software
Regulation	21 CFR 870.2200	21 CFR 870.2200
Generic Device Type	Adjunctive cardiovascular status indicator	Adjunctive cardiovascular status indicator

Characteristic	Subject Device EchoGo Heart Failure 1.0	Predicate Device T3 Platform Software
SaMD	Yes	Yes
Intended Use	Providing adjunctive information on a patient's cardiovascular condition (diagnostic aid for Heart Failure with Preserved Ejection Fraction (HFpEF)).	Providing adjunctive information on a patient's cardiovascular and respiratory condition.
Indications for Use	EchoGo Heart Failure 1.0 is an automated machine learning-based decision support system, indicated as a diagnostic aid for patients undergoing routine functional cardiovascular assessment using echocardiography. When utilised by an interpreting clinician, this device provides information that may be useful in detecting heart failure with preserved ejection fraction (HFpEF). EchoGo Heart Failure 1.0 is indicated in adult populations over 25 years of age. Patient management decisions should not be made solely on the results of the EchoGo Heart Failure 1.0 analysis. EchoGo Heart Failure 1.0 takes as input an apical 4-chamber view of the heart that has been captured and assessed to have an ejection fraction ≥50%.	The T3 Data Aggregation & Visualization software module is intended for the recording and display of multiple physiological parameters of the adult, paediatric, and neonatal patients from supported bedside devices. The software module is not intended for alarm notification or waveform display, nor is it intended to control any of the independent bedside devices to which it is connected. The software module is intended to be used by healthcare professionals for the following purposes: • To remotely consult regarding a patient's status, and • To remotely review other standard or critical near real-time patient data in order to utilize this information to aid in clinical decisions and deliver patient care in a timely manner. The T3 Data Aggregation & Visualization software module can display numeric physiologic data captured by other medical devices: • Airway flow, volume, and pressure • Arterial blood pressure (invasive and non-invasive, systolic, diastolic, and mean) • Bi-spectral index (BIS, signal quality index, suppression ratio) • Cardiac Index • Cardiac output • Central venous pressure • Cerebral perfusion pressure • End-tidal CO2 • Heart rate • Heart rate variability

Characteristic	Subject Device EchoGo Heart Failure 1.0	Predicate Device T3 Platform Software
		• Intracranial pressure • Left atrium pressure • Oxygen saturation (intravascular, regional, SpO2) • Premature ventricular counted beats • Pulmonary artery pressure (systolic, diastolic, and mean) • Pulse pressure variation • Pulse Rate • Respiratory rate • Right atrium pressure • Temperature (rectal, oesophageal, tympanic, blood, core, nasopharyngeal, skin) • Umbilical arterial pressure (systolic, diastolic, and mean The T3 Data Aggregation & Visualization software module can display laboratory measurements including arterial and venous blood gases, complete blood count, and lactic acid. T3 Data Aggregation & Visualization software module can display information captured by the T3 Risk Analytics Engine software module. The T3 Risk Analytics Engine software module calculates four indices: the IDO2 Index for inadequate delivery of oxygen, the IVCO2 Index for inadequate ventilation of carbon dioxide, the ACD Index for acidaemia, and the HLA Index for hyperlactatemia. The IDO2 Index is indicated for use by health care professionals with post-surgical patients 0 to 12 years of age and weighing 2 kg or more under intensive care. The IDO2 Index is derived by mathematical manipulations of the physiologic data and laboratory measurements received by the T3 Data Aggregation & Visualization software module. When the IDO2 Index is

Characteristic	Subject Device EchoGo Heart Failure 1.0	Predicate Device T3 Platform Software
		increasing, it means that there is an increasing risk of inadequate oxygen delivery and attention should be brought to the patient. The IDO2 Index presents partial quantitative information about the patient's cardiovascular condition, and no therapy or drugs can be administered based solely on the interpretation statements. The IVCO2 Index is indicated for use by health care professionals with invasively ventilated patients 0 to 12 years of age and weighing 2 kg or more under intensive care. The IVCO2 Index is derived by mathematical manipulations of the physiologic data and laboratory measurements received by the T3 Data Aggregation and Visualization software module. When the IVCO2 Index is increasing, it means that there is an increasing risk of inadequate carbon dioxide ventilation and attention should be brought to the patient. The IVCO2 Index presents partial quantitative information about the patient's respiratory condition, and no therapy or drugs can be administered based solely on the interpretation statements. The ACD Index is indicated for use by health care professionals with invasively ventilated patients 0 to 12 years of age and weighing 2 kg or more under intensive care. The ACD Index is derived by mathematical manipulations of the physiologic data and laboratory measurements received by the T3 Data Aggregation and Visualization software module. When the ACD Index is increasing, it means that there is an increasing risk of acidaemia and attention should be brought to the patient. The ACD Index presents partial quantitative information about the patient's respiratory condition, and no therapy or drugs can be administered

Characteristic	Subject Device EchoGo Heart Failure 1.0	Predicate Device T3 Platform Software
		based solely on the interpretation statements. The HLA Index is indicated for use by health care professionals with post-surgical patients 0 to 12 years of age and weighing 2 kg or more under intensive care. The HLA Index is derived by mathematical manipulations of the physiologic data and laboratory measurements received by the T3 Data Aggregation & Visualization software module. When the HLA Index is increasing, it means that there is an increasing risk of hyperlactatemia and attention should be brought to the patient. The HLA Index presents partial quantitative information about the patient's cardiovascular condition, and no therapy or drugs can be administered based solely on the interpretation statements.
Population	Adults over the age of 25	Adult, paediatric, and neonatal patients
Anatomical Site	Cardiovascular	Cardiovascular, pulmonary
Users	Interpreting clinician	Healthcare professional
Machine Learning-Based Algorithm	Yes	No
Operating platform	Hosted on Ultromics' platform or on third party infrastructure.	Hosted in hospital infrastructure.
Interoperability	Interoperability testing conducted with device capable of calculating an ejection fraction on the apical 4 chamber view.	Can display numeric physiological data captured by other medical devices.
Software	Complies with IEC 62304:2015 and GPSV. Developed under an FDA QSR and ISO 13485:2016 compliant QMS incorporating risk management per ISO 14971:2019. Software verification and validation testing conducted.	Complies with GPSV and developed under an FDA QSR compliant QMS incorporating risk management. Software verification and validation testing conducted.
Risk Management	In accordance with ISO 14971:2019	Not disclosed
Cybersecurity	Post-market Management of Cybersecurity in Medical Devices. Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.	Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.

Characteristic	Subject Device EchoGo Heart Failure 1.0	Predicate Device T3 Platform Software
	Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software: Guidance for Industry.	
Usability	Complies with IEC 62366-1:2020 and general use of FDA guidance documents on usability engineering. Formative and summative evaluations conducted with accredited cardiac physiologists (N=2) and cardiologists (N=5).	Human factors testing was used to support that the device users can safely use the device.
Pre-clinical Performance Testing	No animal studies were conducted.	No animal studies were conducted.
Bench Performance Testing	Technical validation, numerical stability, and regression testing.	Technical validation.
Clinical Performance Testing	Validated on a US cohort population, comprising 8 independent clinical sites representative of the intended use population.	Validated on a patient cohort (including subpopulation studies neonates, infants, children) representative of the intended use population.

Any technological differences between the subject and predicate devices raise no new concerns with regards to safety and efficacy. In addition, Ultromics is of the view that general controls alongside special controls introduced under the primary product code of the predicate are sufficient to ensure safety and efficacy of the EchoGo Heart Failure 1.0 device.

8 Special Controls

Special controls for regulation 21 CFR 870.2200 (and product code PPW) follows. The submission itself contains detailed references to supporting documentation and/or data allowing the verification of the implementation of the associated special controls.

Control	Description	
1	Software description, verification, and validation based on comprehensive hazard analysis:	
a	Full characterization of technical parameters of the software, including any proprietary algorithm(s)	Control implemented
b	Description of the expected impact of all applicable acquisition hardware characteristics on performance and any associated hardware specifications.	Control implemented
c	Specification of acceptable data quality control measures.	Control implemented
d	Mitigation of impact of user error or failure of any components (data detection and analysis, data display, and storage) on accuracy of patient reports.	Control implemented

2	Scientific justification for the validity of the status indicator algorithm(s) must be provided. Verification of algorithm calculations and validation testing of the algorithm using a data set separate from the training data must demonstrate the validity of modelling.	Control implemented
3	Usability assessment must be provided to demonstrate that risk of misinterpretation of the status indicator is appropriately mitigated.	Control implemented
4	Clinical data must be provided in support of the intended use and include the following:	
a	Output measure(s) must be compared to an acceptable reference method to demonstrate that the output measure(s) represent(s) the predictive measure(s) that the device provides in an accurate and reproducible manner.	Control implemented
b	The data set must be representative of the intended use population for the device. Any selection criteria or limitations of the samples must be fully described and justified.	Control implemented
c	Agreement of the measure(s) with the reference measure(s) must be assessed across the full measurement range.	Control implemented
d	Data must be provided within the clinical validation study or using equivalent datasets to demonstrate the consistency of the output and be representative of the range of data sources and data quality likely to be encountered in the intended use population and relevant use conditions in the intended use environment.	Control implemented
5	Labelling must include the following:	
a	The type of input data used, including specification of compatible hardware for data acquisition.	Control implemented
b	A description of what the device measures and outputs to the user.	Control implemented
c	Warnings identifying acquisition or other factors that may impact output measures.	Control implemented
d	Guidance for interpretation of the output measures, including warning(s) specifying adjunctive use of the results.	Control implemented
e	Key assumptions made in the calculation and determination of results.	Control implemented
f	The measurement performance of the device for all presented parameters, with appropriate confidence intervals, and the supporting evidence for this performance.	Control implemented
g	A detailed description of the patients studied in the clinical validation (e.g., age, gender, race/ethnicity, clinical stability) as well as procedural details of the clinical study.	Control implemented

9 Consensus Standards

The following consensus standards were used in the design and manufacture of EchoGo Heart Failure 1.0.

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
ISO 14155:2020 – Clinical investigation of medical devices for human subjects — Good clinical practice	2-282

Ultromics Limited cites conformity to the voluntary standards above. In addition, EchoGo Heart Failure 1.0 was designed and manufactured under a QMS that fully conforms to ISO 13485:2016.

10 Performance Data

10.1 Software Verification and Validation

EchoGo Heart Failure 1.0 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. Regression- and numerical stability testing were conducted to ensure the device meets algorithmic specifications. Formative and summative usability assessments were conducted to validate labelling and mitigate against the device outputs being misinterpreted by the clinical user. 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 Heart Failure 1.0 passed all software verification and validation tests.

10.2 Essential Performance

Device performance was validated using bench- and clinical performance testing.

An independent clinical validation study was conducted on a clinical data set representative of the intended use population and containing a range of data sources and data quality likely to be encountered in the

intended use population and relevant use conditions in the intended use environment. The study was used to demonstrate consistency of the device output as well as to assess agreement with reference ground truth.

Device performance was determined according to a retrospective case-control study including multiple sites spanning five states in the USA. The final testing data cohort amounted to 1,285 patients, comprising 639 controls and 646 cases. The key results pertaining to the clinical performance testing are summarized below:

1. The device output was compared to the ground truth classifications of cases (HFpEF) or controls. EchoGo Heart Failure 1.0 correctly identified 535 true positives, and 477 true negatives, alongside 105 false positives and 74 false negatives. This equates to a sensitivity of 87.8% (95% CI: 85.0, 90.3%) and a specificity of 82.0% (95% CI: 78.6, 85.0%). The p value for the one-sided binomial exact tests against *a priori* acceptance criteria was $p<0.001$ for both sensitivity and specificity.
2. The device output classification from a single Digital Imaging and Communications in Medicine (DICOM) clip analysed twice (repeatability), and the device output classification from different DICOM clips from the same individual (reproducibility). The device demonstrated 100% repeatability in all measures and 86.7% Positive Agreement, 76.9% Negative Agreement, and 45.5% No classification Agreement for reproducibility.
3. The proportion of non-diagnostic (i.e., "No classification") outputs of the device were within *a priori* acceptance limits. Of the 1,285 studies analysed by the device, 94 (7.3%) were categorized as "No Classification.
4. Additional sub-group analysis was performed for patients prescribed sodium-glucose cotransporter inhibitors (SGLT2i). Point estimates for the device sensitivity for patients on SGLT2i was 80.5%, and specificity was 87.3% on a total of 105 patients.

All measurements produced by EchoGo Heart Failure 1.0 were deemed to be substantively equivalent to the predicate device and met pre-specified levels of performance. We therefore consider EchoGo Heart Failure 1.0 to be substantively equivalent to the predicate device and is therefore deemed to be safe and effective.

11 Conclusions

The subject device, EchoGo Heart Failure 1.0 is as safe and as effective as the predicate device, T3 Platform Software, previously cleared under K213230.

Ultromics concludes that the predicate and subject devices have the same intended use as well as similar technological characteristics. Any minor differences between the subject and the predicate device, as described above, do not alter the intended use of the device, and do not raise new or different questions regarding its safety and effectiveness.

Furthermore, Ultromics believe special controls introduced under the 21 CFR 870.2200 regulation are sufficient to ensure safety and effectiveness. These include: software verification and validation including a comprehensive hazard analysis; validation testing of the AI algorithm using a data set separate from the training data to demonstrate the validity of the device output; a usability assessment; clinical data in support of the intended use; as well as labelling consistent with the intended use. Performance data is provided as part of this PMN application to demonstrate that EchoGo Heart Failure 1.0 performs as intended in the specified use conditions and that it is as safe and effective as the predicate device and therefore substantially equivalent to K213230.