Cycle Clarity
℅ John Schnorr, M.D.
CEO
1209 Fifteen Mile Landing Rd.
AWENDAW SC 29429

January 19, 2022

Re: K212012
Trade/Device Name: Follicle Clarity Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: December 20, 2021
Received: December 21, 2021

Dear Dr. Schnorr:

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*

**K212012**

Device Name
Follicle Clarity Software

Indications for Use *(Describe)*

Follicle Clarity Software is a software application package. It is designed to view and quantify image data acquired on compatible ultrasound systems. Follicle Clarity is used as an aid to interpreting clinicians by calculating the number and size of ovarian follicles in a transvaginal ultrasound volume sweep of the ovaries.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary

# K212012

## I. Submitter's Information

| | |
|---|---|
| Company Name: | Cycle Clarity LLC |
| Address: | 1209 Fifteen Mile Landing Rd.<br>Awendaw, SC 29429 |
| Phone Number: | 843-883-6200 |
| E-mail: | john.schnorr@cycleclarity.com |
| Fax Number: | |
| Contact Person: | John Schnorr, MD |
| Phone Number: | 843-883-6200 |
| Email Address: | john.schnorr@cycleclarity.com |
| | |
| Date Prepared: | June 18, 2021 |

## II. Device Information

| | |
|---|---|
| Device Name: | Follicle Clarity software |
| Common Name: | Picture Archiving and Communications System |
| Regulatory Class: | Class II |
| Regulation: | 21 CFR 892.2050 |
| Product Code: | QIH |

## III. Predicate Device

Predicate Device: QLAB Advanced Quantification Software 13.0, Philips Ultrasound Inc., K191647

Reference Device: Voluson E6/E8/E8 Expert/E10 Diagnostic Ultrasound System, GE Healthcare, K122327

## IV. Device Description

Follicle Clarity is a cloud-based software application package (software as a medical device, SaMD). Follicle Clarity automatically calculates the number and size of hypoechoic structures in the received transvaginal ultrasound images and displays the data graphically and in tabular format in the Follicle Clarity application. Graphic displays include both measurements made by the clinician (as measured by the ultrasonographer) as well as those calculated by Follicle Clarity. Graphs can be adjusted for various views of the data. Ultrasound images received are also displayed within the Application to allow the user to verify the resolution, contrast and anatomic completeness. The user is able to enter patient information such as cycle day, estradiol level and progesterone level in the patient profile for tracking. The user also has the ability to add or delete measurements as they feel are appropriate.

## V. Intended Use

Follicle Clarity Software is a software application package. It is designed to view and quantify image data acquired on compatible ultrasound systems.

## VI. Indications for Use

Follicle Clarity Software is a software application package. It is designed to view and quantify image data acquired on compatible ultrasound systems. Follicle Clarity is used as an aid to interpreting clinicians by calculating the number and size of ovarian follicles in a transvaginal ultrasound volume sweep of the ovaries.

## VII. Technological Characteristics

The technological specifications of Follicle Clarity and its predicate and reference device have been evaluated to determine equivalence. As detailed on Section 012 – *Substantial equivalence* of this 510(k) submission, upon reviewing and comparing intended use, design, materials, principle of operation and overall technological characteristics, Follicle Clarity is determined by Cycle Clarity to be substantially equivalent to existing legally marketed devices (Table 1).

*Table 1: Overview of Substantial Equivalence*

| | QLAB (Predicate Device) | Voluson (Reference Device) | Follicle Clarity (Subject Device) | Equivalence Description |
|---|---|---|---|---|
| **Administrative Information** | | | | |
| **Product Name** | QLAB Advanced Quantification Software 13.0 | Voluson E6/E8/ E8Expert/E10 Diagnostic Ultrasound System | Follicle Clarity Software | N/A |
| **510(k) Holder** | Philips Ultrasound, Inc. | GE Healthcare Austria GmbH & Co OG | Cycle Clarity LLC | N/A |
| **510(k) Number** | K191647 | K122327 | TBD | N/A |
| **Common Name** | Picture Archiving and Communications System | -Ultrasonic Pulsed Doppler Imaging System<br>-Ultrasonic Pulsed Echo Imaging System<br>-Diagnostic Ultrasound Transducer | Picture Archiving and Communications System | Identical to predicate |
| **Regulation** | 21 C.F.R. § 892.2050 | 21 C.F.R. §892.1550<br>21 C.F.R. §892.1560<br>21 C.F.R. §892.1570 | 21 C.F.R. § 892.2050 | Identical to predicate |
| **Product Code** | QIH | IYN, IYO, ITX | QIH | Identical to predicate |
| **Regulatory Class** | II | II | II | Identical to predicate |
| **Intended Use** | | | | |
| **Intended Use** | QLAB Advanced Quantification Software is a software application package. It is designed to view and quantify image data acquired on Philips ultrasound systems. | The device is a general-purpose ultrasound system. Specific clinical applications remain the same as previously cleared: Fetal/OB, Abdominal (including GYN, pelvic and infertility monitoring/follicle development); Pediatric; Small Organ (breast, testes, thyroid, etc.); Neonatal and Adult | Follicle Clarity Software is a software application package. It is designed to view and quantify image data acquired on compatible ultrasound systems. | Same[2]<br>Predicate and subject devices are software intended to quantify image data on compatible ultrasounds.<br>The subject device intended use is the same as the SonoAVC software included in the reference device. |

| | | | | |
|---|---|---|---|---|
| | | Cephalic; Cardiac (adult and pediatric); Musculo-skeletal Conventional and Superficial; Peripheral Vascular; Transvaginal; Transrectal; and Intraoperative (abdominal, PV and neurological).[1] | | |
| **Prescription Only?** | Yes | Yes | Yes | Identical to predicate |
| **Technological Characteristics** | | | | |
| **Application Description** | QLAB software includes multiple features for automated detection and measurement of structures in gynecological, obstetrics, cardiac, and other clinical applications. K191647 describes the particular application for measuring cardiac structures within the ultrasound images using automatic segmentation technology. The software utilizes "locked" (non-adaptive) machine learning algorithms to identify the contours of the targeted structure within the ultrasound image. A report of measurement data is displayed. | SonoAVC software detects hypoechoic structures (i.e., follicles) in transvaginal ultrasound images and measures their size. The software utilizes algorithms to identify the contours of the targeted structure within the ultrasound image. A report of measurement data is displayed. | Follicle Clarity software detects hypoechoic structures (i.e., follicles) in transvaginal ultrasound images and measures their size. The application measures structures within the ultrasound images using automatic segmentation technology. The software utilizes "locked" (non-adaptive) machine learning algorithms to identify the contours of the targeted structure within the ultrasound image. A report of measurement data is displayed. | Equivalent<br>All of the software systems utilize proprietary algorithms to detect and quantify structures within ultrasound images. Subject and predicate devices utilize machine learning/AI algorithms to identify specific contours of the anatomy using automatic segmentation technology and quantify structures based on this analysis.<br>Subject and reference devices specifically detect and analyze follicle number and size. |
| **Target User Population** | Interpreting clinicians | Interpreting clinicians | Interpreting clinicians | Identical to predicate |
| **How Supplied?** | Software application | Software application (SonoAVC software is supplied with the Voluson ultrasound hardware) | Software application | Identical to predicate |
| **Use of machine learning algorithm?** | Yes | Unknown | Yes | Identical to predicate |
| **Required Patient Clinical Data (Imaging) Format** | DICOM | NA | DICOM | Identical to predicate |
| **Ultrasound Compatibility** | Philips | Voluson E6/E8/E8Expert/E10 | - Voluson, E6, E8, E10<br>- Philips<br>- Siemens Acuson Version | Equivalent<br>Subject device has been validated to process ultrasound images from Philips and Voluson ultrasound systems and others. |

[1] The reference device intended use and indications for use pertain to the Voluson ultrasound system. SonoAVC is a software component of the Voluson system and intended for the same use as the subject device (as labeled): Sonography-based Automated Volume Count follicle (SonoAVC follicle) automatically calculates the number and volume of hypoechoic structures in a volume sweep.

The technological differences between the predicate and subject device do not impact the safety and effectiveness of the subject device as described in Section 012 – *Substantial Equivalence*.

## VIII. Performance Data

Performance Testing conducted to evaluate and compare the technological and performance characteristics included non-clinical performance testing and clinical studies.

Non-Clinical

Design Control activities to assure the safe and effective performance of Follicle Clarity included but were not limited to the following:

- Requirements Review
- Design Review
- Risk Management
- Software Verification and Validation

Non-clinical V&V testing included the Machine Learning Algorithm Training and the subsequent Validation Studies performed for the proposed application. Pre-determined performance specifications were tested, and verification and validation activities conducted to demonstrate that the Follicle Clarity met the defined performance criteria.

Validation of the tracking and measurement accuracy of the platform was conducted through a phantom trial in which manual measurements of phantom targets were conducted within a DICOM viewer and compared to Follicle Clarity results. A second validation trial compared ovarian follicle measurements in ovaries with 3 or less follicles per ovary in which manual measurements of follicles were conducted within a DICOM viewer and compared to Follicle Clarity results. A third validation trial compared ovarian follicle measurements in ovaries with 10 or greater follicles per ovary in which manual measurements of follicles were conducted within a DICOM viewer and compared to Follicle Clarity results. All three validation trials demonstrated that in a 1:1 (follicle to follicle) comparison, that Follicle Clarity tracking and measurement accuracy was within the margin of error for human measurements.

Clinical

Clinical validation of the Follicle Clarity application was performed in a prospective study to evaluate the accuracy, precision, and level of agreement of a Follicle Clarity in comparison to manual (ultrasonographer) measurements and SonoAVC measurements. The primary endpoint was the median size (mm) of ovarian follicles measured by Follicle Clarity compared to SonoAVC. The secondary endpoint was the number of ovarian follicles identified by Follicle Clarity compared to SonoAVC. In all cases, Follicle Clarity met the predetermined endpoints and demonstrated substantially equivalent performance in identifying the number and size of follicles.

## IX. Conclusion

Follicle Clarity has the same intended use as the QLAB software and SonoAVC (Voluson E6/E8/E8 Expert/E10 Diagnostic Ultrasound System) software. The conclusion drawn from the nonclinical and clinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device. The design/technological differences do not raise any

new types of questions and the performance data provided reasonable assurance of safety and effectiveness to demonstrate substantial equivalence.