MIM Fertility
% Mariel Chavez
Regulatory Specialist
Prime Path Medtech
1321 Upland Dr.
Suite 6792
Houston, Texas 77043

April 20, 2026

Re: K252332
Trade/Device Name: Folliscan
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: March 6, 2026
Received: March 6, 2026

Dear Mariel Chavez:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Lamb, Ph.D
Assistant Director
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K252332

Device Name

Folliscan

Indications for Use *(Describe)*

FOLLISCAN is a software application package. It is designed to quantify image data acquired on compatible ultrasound systems. FOLLISCAN is used as an aid to clinicians to interpret images 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.

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510(k) Summary

510(k) SUMMARY

A 510(k) summary for this traditional 510(k) in accordance with the requirements of 21 CFR 807.92.

Submitter: MIM Fertility
Swieradowska 47, 02-662,
Warszawa Poland

Company Contact Person: Urszula Sankowska
Phone: +48 606 366 958
Email: Ula@mimfertility.ai

Submission Correspondent: Mariel Chavez, Regulatory Affairs Consultant
Address: 1321 Upland Dr. Suite 6792 Houston, TX 77043
Phone: +1 954-260-0026
Email: mchavez@primepathmedtech.com

Date Prepared: 10 April 2026

Proprietary Name: Folliscan

Common Name: Automated Radiological Image Processing Software

Product Code: QIH

Device Classification: Class II, 21 CFR 892.2050

Primary Predicate Device: Follicle Clarity (K212012)

Device Description:

The FOLLISCAN application is a medical software product based on artificial intelligence algorithms that provides information on the number and size of ovarian follicles based on cine loop videos (both 2D and 3D) from transvaginal ultrasound examinations used in the process of monitoring ovulation during ovarian ultrasound examination.

The primary functions of FOLLISCAN is the semi-automatic measurement and tracking of follicle size and count.

FOLLISCAN medical device can be used through a web browser or through a programmatic API using a validated connector.

The obtained results should be verified manually using DICOM viewer before clinical usage

Indications for Use:

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

Comparison to Predicate Devices:

The Subject Device is functionally equivalent to the predicate device. The following table demonstrates the functional specifications of the Subject Device are substantially equivalent to the Predicate Device and raise no new questions regarding safety and effectiveness of the device.

Device Comparison Table

Specification	**Subject Device:** FOLLISCAN	**Predicate Device:** Follicle Clarity	**Comparison Result**
Administrative Information			
Product Name	FOLLISCAN Software	Follicle Clarity Software	N/A
510(k) Holder	MIM Fertility	Cycle Clarity LLC	N/A
510(k) Number	K252332	K212012	N/A
Common Name	Picture Archiving and Communication System	Picture Archiving and Communication System	Identical to predicate
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	Identical to predicate
Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological	Identical to predicate
Product Code	QIH	QIH	Identical to predicate
Regulatory Classification	Class II	Class II	Identical to predicate
Intended Use			
Intended Use	FOLLISCAN is a software application package designed to view and quantify image data acquired on compatible ultrasound systems.	Follicle Clarity Software is a software application package. It is designed to view and quantify image data acquired on compatible ultrasound systems.	Identical to predicate. Predicate and subject devices are both software medical devices intended to quantify image data on compatible ultrasound systems.
Prescription Only?	Yes	Yes	Identical to predicate
Technological Characteristics			

Application Description	The FOLLISCAN application is a medical software product based on artificial intelligence	Follicle Clarity software detects hypoechoic structures (i.e., follicles) in transvaginal	Equivalent. Both software systems utilize

Specification	**Subject Device:** FOLLISCAN	**Predicate Device:** Follicle Clarity	**Comparison Result**
	algorithms that provide information on the number and size of ovarian follicles based on cine loop videos (both 2D and 3D) from transvaginal ultrasound examinations used in the process of monitoring ovulation during ovarian ultrasound examinations.	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.	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. Both devices specifically detect and analyze follicle number and size.
Target User Population	Interpreting clinicians	Interpreting clinicians	Identical to predicate
How Supplied?	Software application	Software application	Identical to predicate
Use of machine learning algorithm?	Yes	Yes	Identical to predicate
Required Patient Clinical Data (Imaging) Format	DICOM	DICOM	Identical to predicate

Ultrasound Compatibility	- Siemens ACUSON NX3 - Samsung HERA W9 - GE Voluson GE Voluson P8 - GE Voluson E8 - BK Medical Sonix - S10	- Voluson, E6, E8, E10 - Philips - Siemens Acuson Version	Equivalent. The subject device has been proven to be compatible and able to process any ultrasound that has a DICOM standard connectivity enabled.

Comparison of Indications for Use to the Predicate Device:

FOLLISCAN is a software application package designed to view and quantify image data acquired on compatible ultrasound systems.

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

The indications for use of FOLLISCAN are identical to those of the predicate device. Both devices are intended to view and quantify image data obtained from compatible ultrasound systems for clinical use.

Comparison of Technological Characteristics to Predicate Device:

FOLLISCAN is a software-based medical device that utilizes artificial intelligence (AI)-based algorithms to analyze transvaginal ultrasound cine-loop data (2D and 3D). The software identifies and quantifies ovarian follicles by providing measurements of follicle number and size.

The predicate device, Follicle Clarity Software, is a software application that detects hypoechoic structures (i.e., ovarian follicles) in transvaginal ultrasound images and measures their size using automatic segmentation technology. The software employs “locked” (non-adaptive) machine learning algorithms to identify the contours of the targeted structures and generates a report of measurement data.

Both FOLLISCAN and Follicle Clarity are software-based devices that analyze transvaginal ultrasound data to detect and measure ovarian follicles. Both devices utilize algorithm-based image processing techniques, including machine learning-based segmentation, to identify follicular structures and provide quantitative measurement outputs for clinical use.

Differences between the devices include the type of input data and implementation of algorithms. FOLLISCAN is designed to process cine-loop ultrasound data (2D+t) and 3D datasets, whereas Follicle Clarity is designed to analyze ultrasound images. Additionally, while both devices utilize machine learning-based approaches for structure identification, Follicle Clarity explicitly employs “locked” (non-adaptive) algorithms, and FOLLISCAN similarly utilizes fixed algorithms that do not adapt or change during clinical use.

These differences in technological characteristics do not alter the fundamental principles of operation, as both devices rely on established image analysis and segmentation techniques to identify and measure

ovarian follicles from ultrasound data. The similarities in intended functionality and underlying technology support that these differences do not raise new questions of safety and effectiveness.

Summary of Performance Data

Nonclinical testing was conducted to include: software verification & validation, risk management assessments, requirements review and traceability, and design review. The nonclinical and clinical testing conducted on the Folliscan device demonstrates that it is as safe, as effective, and performs as well as or better than the legally marketed predicate device. Because the Folliscan is a software-only device that retrospectively analyzes existing transvaginal ultrasound cine-loops and 3D scans without patient contact, energy application, or alteration to clinical management, it presents no additional safety risks, and no device-related adverse events or complications were observed or expected during testing.

Primary Endpoint	**Acceptance Criteria**	**Values (95% CI)**
Ovary Count Agreement (global)	<10 mm: |Δcount| ≤ ±5 follicles per ovary - Wilson test 95% Lower bound≥0,70 ≥10 and <17 mm: |Δcount| ≤ ±2 follicles per ovary - Wilson test Lower bound≥0,70 ≥17 mm : |Δcount| ≤ ±1 follicle per ovary - Wilson test Lower bound≥0,70	<10 mm: 0.920 (0.863, 0.955) ≥10 and <17 mm: 0.957 (0.908,0.980) ≥17 mm: 0.957 (0.908, 0.980)
Ovary Count Agreement (US)	<10 mm: |Δcount| ≤ ±5 follicles per ovary - Wilson test 95% Lower bound≥0,70 ≥10 and <17 mm: |Δcount| ≤ ±2 follicles per ovary - Wilson test Lower bound≥0,70 ≥17 mm : |Δcount| ≤ ±1 follicle per ovary - Wilson test Lower bound≥0,70	<10 mm: 0.978 (0.884, 0.996) ≥10 and <17 mm: 0.911 (0.793,0.965) ≥17 mm: 0.911 (0.793, 0.965)

Ovary Count Agreement (OUS)	<10 mm: |Δcount| ≤ ±5 follicles per ovary - Wilson test 95% Lower bound≥0,70 ≥10 and <17 mm: |Δcount| ≤ ±2 follicles per ovary - Wilson test Lower bound≥0,70 ≥17 mm : |Δcount| ≤ ±1 follicle per ovary - Wilson test Lower bound≥0,70	<10 mm: 0.892 (0.813, 0.941) ≥10 and <17 mm: 0.978 (0.925,0.994) ≥17 mm: 0.978 (0.925, 0.994)
Measurement Accuracy RMSE d1 (global)	Upper 95% CI bound for RMSE d1 ≤ 2.0 mm	1.021 (0.934, 1.109)
Measurement Accuracy RMSE d1 (US)	Upper 95% CI bound for RMSE d1 ≤ 2.0 mm	1.195 (1.038, 1.365)
Measurement Accuracy RMSE d1 (OUS)	Upper 95% CI bound for RMSE d1 ≤ 2.0 mm	0.940 (0.838, 1.047)
Measurement Accuracy Bias d1 (global)	Upper 95% CI bound for |bias d1| ≤ 1.0 mm	-0.532 (-0.581, -0.485)
Measurement Accuracy Bias d1 (US)	Upper 95% CI bound for |bias d1| ≤ 1.0 mm	-0.612 (-0.725, -0.509)
Measurement Accuracy Bias d1 (OUS)	Upper 95% CI bound for |bias d1| ≤ 1.0 mm	-0.499 (-0.553, -0.448)
Measurement Accuracy RMSE d2 (global)	Upper 95% CI bound for RMSE d2 ≤ 2.0 mm	0.779 (0.715, 0.846)
Measurement Accuracy RMSE d2 (US)	Upper 95% CI bound for RMSE d2 ≤ 2.0 mm	0.927 (0.806, 1.059)
Measurement Accuracy RMSE d2 (OUS)	Upper 95% CI bound for RMSE d2 ≤ 2.0 mm	0.710 (0.634, 0.786)
Measurement Accuracy Bias d2 (global)	Upper 95% CI bound for |bias d2| ≤ 1.0 mm	-0.330 (-0.368, -0.290)
Measurement Accuracy Bias d2 (US)	Upper 95% CI bound for |bias d2| ≤ 1.0 mm	-0.419 (-0.507, -0.336)
Measurement Accuracy Bias d2 (OUS)	Upper 95% CI bound for |bias d2| ≤ 1.0 mm	-0.293 (-0.337, -0.250)
Measurement Accuracy RMSE volume (global)	Upper 95% CI bound for RMSE volume ≤ 1.0 mL (1000 mm^3)	13.923 (11.742, 16.094)

Measurement Accuracy Bias volume (global)	Upper 95% CI bound for bias volume ≤ 0.5 mL (500 mm^3)	-2.822 (-4.267, -1.340)

Table 1. Summarizing the performance data - primary endpoints

Secondary Endpoint	**Value**
MAE Δcount (global)	2.101 (1.761-2.471)
MAE Δcount (US)	1.400 (0.956-1.911)
MAE Δcount (OUS)	2.441 (1.989-2.925)
Precision (global)	90.2 (88.3-92.0)
Precision (US)	89.2 (85.7-92.3)
Precision (OUS)	90.6 (88.2-92.9)
Recall (global)	77.6 (74.9-80.1)
Recall (US)	80.0 (76.1-83.7)
Recall (OUS)	76.7 (73.3-80.0)
F1 Score (global)	83.4 (81.5-85.2)
F1 Score (US)	84.4 (81.3-87.0)
F1 Score (OUS)	83.1 (80.6-85.4)

Table 2. Summarizing the performance data - secondary endpoints

Taken together, these results demonstrate that the Folliscan device provides clinically accurate and reliable automated follicle detection, counting, and measurement across a diverse, multi-site, multi-scanner dataset, and that it is substantially equivalent to the identified predicate device.

AI Ground Truth and Data Independence:

Ground truth for the held-out test set was established using a multi-stage, fully manual annotation and expert-validation workflow. All scans were first annotated with tracked follicle boxes, and pixel-level instance masks were then created and refined with access to the full temporal context of each recording. Gynecology experts, blinded to device outputs and clinical outcomes, reviewed the annotations, identified missing follicles, corrected inaccurate masks, removed non-follicular structures, and only expert-approved annotations were retained in the final reference dataset. The resulting reference standard comprised per-ovary follicle counts in clinical size bins and manual follicle measurements derived from the final contour annotations. No synthetic or automatically generated annotations were used in training, validation, or testing.

The development dataset was collected from 2,132 patients between June 2019 and September 2025 across seven fertility centers in Poland, Australia, Argentina, Chile, Turkey, and the United States, totaling 6,404 DICOM files. These data were split into 5,972 training scans and 294 validation scans, while the held-out test set comprised 138 scans from 64 patients obtained from five clinics, including 45 scans from Advanced Fertility Center of Texas (United States). Dataset independence was verified by maintaining distinct training, validation, and test cohorts for model fitting, hyperparameter selection, and final performance evaluation, respectively. In addition, AFC Texas was reserved entirely for the held-out test set and was not used during training or validation; scans acquired on BK Medical Sonix and GE Voluson P8 systems originated exclusively from this held-out U.S. site, providing an additional site-and scanner-level check of independence. Even where some clinics contributed data to both development and test splits, the recordings used for testing were different from those used for training or validation. Moreover, no images of the same patient are shared between training, validation and test datasets.

Conclusion:

Based on the comparisons described above, the subject device, FOLLISCAN, has the same intended use as the predicate device, Follicle Clarity (K212012), and similar technological characteristics. Any differences in technological characteristics, including the type of input data and algorithm implementation, do not raise new questions of safety and effectiveness.

Therefore, FOLLISCAN is substantially equivalent to the legally marketed predicate device, Follicle Clarity (K212012).