April 21, 2023

Elaitra Ltd
% Stephen Morrell
Managing Director
8B Buckland Crescent, Belsize Park
London, NW3 5DX
UNITED KINGDOM

Re: K223501
Trade/Device Name: ViewFinder Software Version 1.1
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: March 23, 2023
Received: March 24, 2023

Dear Stephen Morrell:

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,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223501

Device Name
ViewFinder Software (Version 1.1)

Indications for Use *(Describe)*
ViewFinder is a dedicated softcopy review environment for both screening and diagnostic digital breast tomosynthesis. Its user interface and workflow have been optimized to support qualified interpreting physicians in both screening and diagnostic reading. Efficiency and reading quality are supported by various specialized features. ViewFinder provides visualization and image enhancement tools to aid a qualified interpreting physician in the review of digital breast tomosynthesis datasets. The qualified interpreting physician is responsible for making the diagnosis of the images presented.

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: K223501

Company: Elaitra Ltd
8B Buckland Crescent, Belsize Park
London, NW3 5DX, UK

Date Prepared: April 20, 2023

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. **Submitter**

   Importer / Distributor:
   To be determined
   Establishment Registration Number:

   Location of Manufacturing Site:
   8B Buckland Crescent, Belsize Park
   London, NW3 5DX, UK
   Establishment Registration Number:

2. **Contact Person:**
   Stephen Morrell
   Chief Executive Officer
   Elaitra Ltd
   8B Buckland Crescent, Belsize Park
   London, NW3 5DX, UK
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   Alternate Contact Person:
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   London, NW3 4QS, UK
   michael.hutel@kcl.ac.uk

3. **Device Name and Classification**

Trade Name:	ViewFinder Software Version 1.1
Classification Name:	Medical image management and processing system
Classification Panel:	Radiology
Intended Submission Type:	510(k) Traditional
Classification Regulation:	21 CFR §892.2050
Device Class:	Class II

Product Code:	QIH
Level of Concern	Moderate

Predicate

4. Legally Marketed Predicate Device

Trade/Device Name:	MAMMOVISTA B.smart
510(k) number:	K212621 (Cleared November 12, 2021)
Classification Name:	Medical image management and processing system
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.2050
Device Class:	II
Product Code:	LLZ
Level of Concern	Moderate

Device Description:

5. Description Summary

ViewFinder is software which displays two Digital Breast Tomosynthesis (DBT) views of the same breast and dynamically indicates correlated (matched) tissue. The benefit is that clinicians can compare matched tissue quickly and with less cognitive load.

It works by simulating the tissue movements between Cranio-Caudal (CC) and Medio-Lateral Oblique (MLO) compressions and views for a gross approximation of tissue matching, followed by a second fine tuning using locked Artificial Intelligence (AI). Users operate the device by pointing the cursor at tissue in one view and ViewFinder indicates the matching tissue in the other view.

ViewFinder is a standalone software application or can be integrated into medical image management and processing systems. ViewFinder is an image viewing and processing software environment dedicated to breast image display.

It is designed to provide the performance required for the high data volume of DBT.

ViewFinder runs on a PC and can be used for digital breast tomosynthesis image review together with monitors cleared for mammography diagnostics.

6. Indications for Use:

ViewFinder is a dedicated softcopy review environment for both screening and diagnostic digital breast tomosynthesis. Its user interface and workflow have been optimized to support qualified interpreting physicians in both screening and diagnostic reading. Efficiency and reading quality are supported by various specialized features. ViewFinder provides visualization and image enhancement tools to aid a qualified interpreting physician in the review of digital breast tomosynthesis datasets. The qualified interpreting physician is responsible for making the diagnosis of the images presented.

Comparison
The Indications for Use statement for ViewFinder is not identical to the predicate device; however, the differences 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 have the same intended use for assisting reading DBT and mammogram images.

Substantial Equivalence

7. **Substantial Equivalence:**
   Refer to the Predicate Comparison Table below.

   ViewFinder Software is substantially equivalent to the commercially available MAMMOVISTA B.smart software (K212621, cleared November 12, 2021).

   The device remains within the same classification regulation for the same technology as the predicate device. The new software design was completed in accordance with Quality Management System Design Controls under IEC 62304. The scope of internationally recognized standards compliance includes those recognized at the time of the design of the software.

   The intended use of the subject device is a subset of the predicate's intended use. The predicate has an identical feature (Link Views, chapter 6 of the Operator Manual) to the subject device as well as many other additional features (segmentation tools, magnifier, movie mode, viewing Computer Aided Detection and Decision Support, etc. as described in the remaining 12 chapters). Therefore, the intended use differences pose no additional safety or effectiveness concerns.

8. **Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:**
   ViewFinder Software is a software-only solution to run on compatible client server environment together with monitor displays cleared for Mammography.

   The predicate device includes a feature called "Link Views" which matches correlating tissue between two 3D (DBT) images. (It also matches tissue between 2D and 3D images).

   The predicate device has features which the subject device does not. These include interactive decision support powered by Artificial Intelligence by Transpara™, ScreenPoint Medical.

   The following table compares the main performance data of the subject device with the predicate device.

Comparison Table

Comparison of the Subject Device (ViewFinder Software Version 1.1) to Predicate Device (MAMMOVISTA B.smart)

Feature	Subject device	Predicate device (K212621)	Comparison	Impact to Safety & Effectiveness
Regulation Description	System, image processing, radiological	System, image processing, radiological	Equivalent	None
Device name and version (K number)	**ViewFinder Software Version 1.1**	**MAMMOVISTA B.smart Software**	Different	None
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	Equivalent	None
Classification Product Code	QIH	LLZ	Equivalent	None
Manufacturer	Elaitra Ltd	Siemens. Medical Systems, Inc.	Different manufacturer	None
Indications for Use	ViewFinder is a dedicated softcopy review environment for both screening and diagnostic digital breast tomosynthesis. Its user interface and workflow have been optimized to support qualified interpreting physicians in both screening and diagnostic reading. Efficiency and reading quality are supported by various specialized features. ViewFinder provides visualization and image enhancement tools to aid a qualified interpreting physician in the review of digital breast tomosynthesis datasets. The qualified interpreting physician is responsible for	MAMMOVISTA B.smart is a dedicated softcopy review environment for both screening and diagnostic mammography as well as digital breast tomosynthesis. Its user interface and workflow have been optimized to support experienced mammography and tomosynthesis reviewers in both screening and diagnostic reading. Efficiency and reading quality are supported by various specialized features. MAMMOVISTA B.smart provides visualization and image enhancement tools to aid a qualified radiologist in the review of digital mammography and digital breast tomosynthesis datasets, as well as	Equivalent The subject device is more explicit. The predicate device includes multi-modality images (e.g., MRI and ultrasound).	None

Feature	Subject device	Predicate device (K212621)	Comparison	Impact to Safety & Effectiveness
	making the diagnosis of the images presented.	other modalities of breast images.		
Architecture	Client / server environment	Client / server environment	Equivalent	None
Display of 3rd party Computer Aided Diagnostics (CAD) markers	No	Yes	The subject has fewer functions	None
Display and processing of DBT images	Yes	Yes	Equivalent	None
DICOM 3.0	Yes	Yes	Equivalent	None
DICOM compatible modalities	MG Tomo (Mammography Tomosynthesis images) DICOM DSR (Deformable Spatial Registration)	MG (Digital Mammography X-Ray) MG Tomo (Mammography Tomosynthesis images) MR (Magnetic Resonance) US (Ultrasound)	The subject has an additional conformant modality storing tissue correlation. The subject omits MR and US	None
Display of breast density values	No	Yes	The subject has fewer functions	None
Ipsilateral DBT tissue registration	Yes	Yes	Equivalent	None
DBT Registration Algorithms	Finite Element Model and Deep Learning	Finite Element Model	ViewFinder's Deep Learning improves accuracy	No detrimental impact
Measurements	Distance measurements	Distance and angle measurements	The subject device excludes angle measurements	No detrimental impact
Supported Image Generating Manufacturers and Models	Only DBTs produced on Hologic's Selenia Dimensions and GE Healthcare's SenoClaire and Senographe Pristina	No restriction given for manufacturer or model.	The subject device is restricted to fewer manufacturers and models. It does not process combinations which are out of scope.	None

Conclusion Regarding Differences
There are no differences between the subject device and the predicate(s) with respect to indications and intended use which impact safety and effectiveness.

9. Summary of Non-Clinical Tests:

Non-clinical tests were conducted for the ViewFinder software during product development. The ViewFinder software conforms to the following voluntary standards:

Standards Reference Number and Date	Title of Standard
ISO 14971: 2019	Medical devices – application of risk management to medical devices
IEC 62304:2006/A1:2016	Medical device software - Software life cycle processes
NEMA PS 3.1 - 3.20 2016	Digital Imaging and Communications in Medicine (DICOM) Set
IEC 82304-1: 2016	Health software – Part 1: General requirements for product safety

Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued on May 11, 2005, is also included as part of this submission.

Non-clinical tests (integration and functional) were conducted on the ViewFinder during product development. The risk analysis was completed, and risk controls were implemented, to mitigate identified hazards. The test results support that all the software specifications have met the acceptance criteria. Verification and validation testing were found acceptable to support the claim of substantial equivalence.

Elaitra did not conduct any clinical tests for the subject device.

ViewFinder uses a registration process to map tissue coordinates from one compression view to the other based on the different view angles during the acquisitions. ViewFinder uses proprietary Artificial Intelligence and Machine Learning algorithms. The algorithms are 'locked' so that their output only changes in the laboratory under controlled conditions and do not change in the field. This follows the FDA's current classification framework for AI and ML algorithms. The algorithm's predictions only change when a new version of the software is released. The algorithm was trained on a large, diversified set of Tomo cases with ground truth annotations made by a consultant radiologist. There was no overlap between training and test data.

Supporting Scientific Data

The scientific data showing that ViewFinder is as safe and effective as the predicate consists of test result data. These are the correct mapping percentage (where the ground truth matching tissue is inside the target area) and a sample of Total Registration Errors (TRE) on a set of 34 lesions for which locations were available. These were selected from a set of 30 diverse cases acquired from assessment clinics at the King's College Hospital. These cases were selected for their high prevalence of difficult and cancerous cases which makes them suitable for algorithm testing.

Primary Performance Metric: Frequency

The table below shows the stratified ViewFinder performance as measured by the frequency that the ground truth matching tissue is inside the predicted region shown by the oval, stratified by BI-RADS Atlas 5th edition breast density classes A-D and feature size in square millimeters. The count of feature matches in both directions (CC to MLO and MLO to CC) is shown in brackets as the numerator, with the total number of features shown as the denominator. The total number of features is 34 (giving 68 matches including both directions) which exceeds the number of cases because some cases have more than one feature. The total number of patients was 28. It is, therefore, more appropriate to measure performance by feature than by case. The minimum performance threshold is 70% which is exceeded in aggregate and for the majority of subgroups.

The most relevant clinical subgroups and confounders are breast density and feature size, for which performances are shown separately in the performance table below.

Frequency that ground truth is inside oval (n)		**Density**				
Cancer Status	**Feature Size (mm^2)**	**A**	**B**	**C**	**D**	**Grand Total**
All Patients	0 - 40	1.000 (1/1)	0.739 (17/23)	1.000 (7/7)	0.000 (0/)	0.806 (25/31)
	40 - 200	1.000 (1/1)	0.700 (7/10)	1.000 (1/1)	0.000 (0/)	0.750 (9/12)
	200- 500	0.000 (0/)	1.000 (3/3)	1.000 (5/5)	1.000 (2/2)	1.000 (10/10)
	>500	1.000 (2/2)	1.000 (6/6)	0.857 (6/7)	0.000 (0/)	0.933 (14/15)
	Total	1.000 (4/4)	0.786 (33/42)	0.950 (19/20)	1.000 (2/2)	0.853 (58/68)
	Number of cases	2	16	9	1	28

Patient Age Distribution

The test set has a median age of 58 years and 6 months, slightly lower than the mid-point of the UK screening age range of 50 - 70 years. This is shown in the figure below. It is consistent with the screening age recommendations in the USA: "The United States Preventive Services Task Force USPSTF recommends that women who are 50 to 74 years old and are at average risk for breast cancer

get a mammogram every two years. Women who are 40 to 49 years" have an option. (Source: https://www.cdc.gov/cancer/breast/basic_info/screening.htm.)

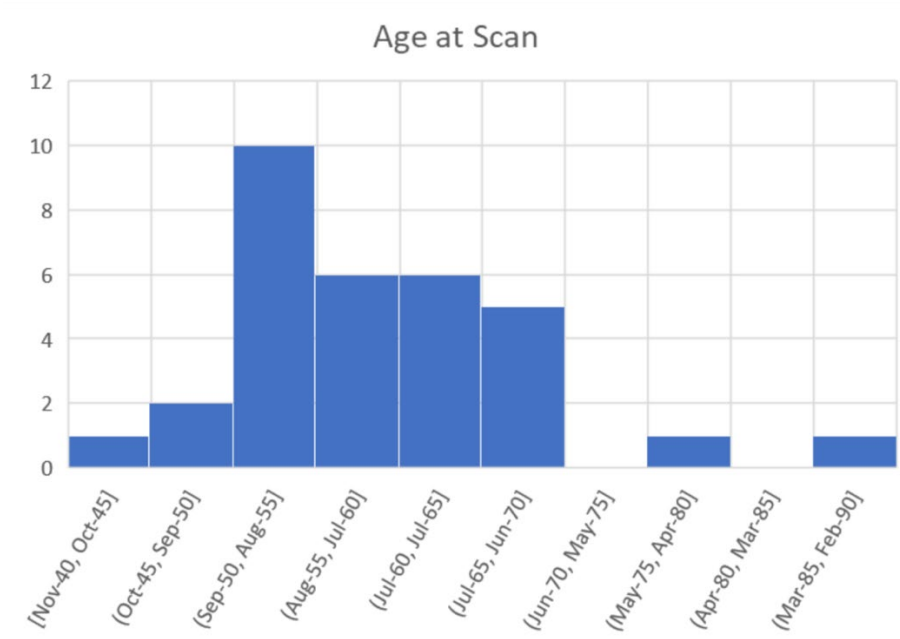

Figure: Histogram of patient ages at scan showing consistency with USA screening guidelines.

Race

The distribution of race between the target population (USA) and the Test Set is sufficiently similar that it would not preclude generalization as shown in the figure below.

The gender of the test set is all women which is consistent with the population of patients in the USA as recommended for the subject device.

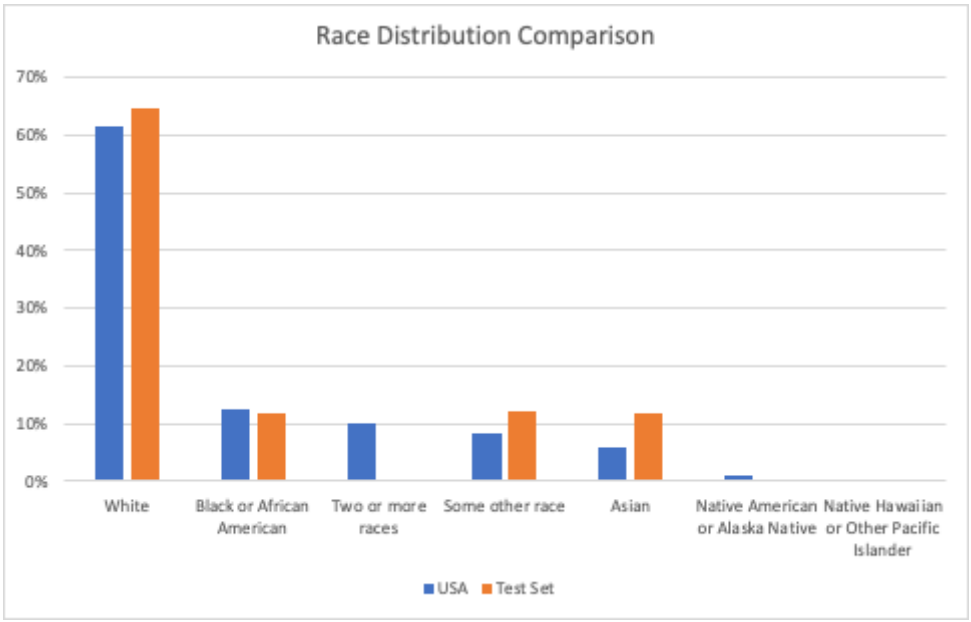

Figure: Race distribution comparison

The test data collection resulted in a test set which consists of 34 CC-MLO pairs of key points in 30 cases acquired from assessment clinics at the King's College Hospital (KCH) from April 2018 to November 2021. These cases were selected for their diversity of diagnoses whose diversity makes them suitable for both human training and algorithm testing. The key points were identified by an expert radiologist at KCH.

Ground truth annotations were made by an expert radiologist.

Upon completion of the Radiologist's annotations, a technical review was conducted through visualization, checking bounding box placement, tissue matches, and that the sequence numbers and pairing were consistent.

Regarding the details for training data: the training data consisted of two datasets consisting of FFDMs drawn from both screening and screening assessment cases and 660 Tomos which were drawn from assessments. The images include two views of each breast, viz. Cranio-caudal and Medio-lateral oblique. The annotations included bounding boxes around landmark tissue. The finding class was used during pre-training (cancerous, benign or normal) with significant representation in each class.

The correct mapping percentage and TREs were from comparisons between ground truths and ViewFinder's predictions in both registration directions (CC to MLO and vice versa).

10. General Safety and Effectiveness Concerns:

Instructions for use are included within the device labeling and the information provided will enable the user to operate the device in a safe and effective manner. Several safety features including visual and audible warnings are incorporated into the system design.

Risk management is ensured via a hazard analysis which is used to identify potential hazards. These potential hazards are controlled via software development, verification, and validation testing.

Furthermore, the operators are qualified healthcare professionals familiar with and responsible for the review of digital mammography images and digital breast tomosynthesis datasets.

11. Regulatory History

There is no regulatory history for this device or this company with the FDA.

In the UK, the device was registered as a Class I Device with the Medicines and Healthcare products Regulatory Agency (MHRA) in October 2021.

12. Conclusion as to Substantial Equivalence:

The ViewFinder's Indication for Use is similar to that of the predicate device. The operating environment and software design are similar. Image display devices (monitors) with the same or similar specifications will be used to display the mammography images.

Verification and validation testing demonstrate that the ViewFinder performs as intended. The non-clinical test data demonstrate that the ViewFinder device performance is comparable to the predicate device that is currently marketed for the same intended use.

It is Elaitra's opinion that the ViewFinder does not introduce any new potential safety risks and is substantially equivalent to the predicate.

13. Guidance documents

The following FDA guidance documents were utilized in this Premarket Notification:

Content of Premarket Submission for Management of Cybersecurity in Medical Devices - Guidance for Industry and Food and Drug Administration Staff
Document Issued on October 2, 2014

Guidance for Industry and FDA Staff - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
Document issued on May 11, 2005

Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices - Guidance for Industry and Food and Drug Administration Staff
Document issued on September 14, 2018.

The 510(k) Program: Evaluation Substantial Equivalent in Premarket Notifications 510(k) - Guidance for Industry and Food and Drug Administration Staff.
Document issued on July 28, 2014.

Off-The-Shelf Software Use in Medical Devices - Guidance for Industry and Food and Drug Administration Staff
Document issued on September 27, 2019.