April 14, 2022

BB Imaging
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

Re: K220767
Trade/Device Name: TeleScan™
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: March 15, 2022
Received: March 16, 2022

Dear Prithul Bom:

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

Jessica Lamb, Ph.D.
Assistant 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)*
K22O767

Device Name
TeleScan™

Indications for Use *(Describe)*

TeleScan™ is a software application that is intended for use in receiving, processing, manipulating, displaying, printing, and archiving ultrasound medical images and data. Images and data can be stored, communicated, and displayed within the system or across computer systems. TeleScan™ provides various image processing and measurement tools to facilitate the interpretation of ultrasound DICOM medical images and enable diagnosis.

TeleScan™ is used by appropriately trained healthcare professionals, including radiologists, sonographers, technologists, and clinicians, in a medical facility. TeleScan™ may provide information to be used for screening and diagnostic procedures. TeleScan™ allows remote qualified radiologists and clinicians to provide a diagnosis remotely.

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

This 510(k) Summary is submitted in accordance with the requirements specified in 21 CFR 807.92.

Date:	March 7, 2022
Submission Sponsor:	BB Imaging 9701 Brodie Lane, Suite 200 Austin, TX 78748
Contact Person:	Blanca Lesmes CEO, BB Imaging Tel: 1.844.766.6111
Trade or Proprietary Name:	**TeleScan™ (K220767)**
Common or Usual Name:	Medical image management and processing system
Regulatory Number:	21 CFR 892.2050
Product Code:	LLZ (System, Image Processing, Radiological)
Device Class:	Class II
Panel:	Radiology
Predicate Device:	Unifi Workspace v1.0.0 (K190694)
510(k) Submitter/Holder:	Hologic, Inc.
Regulatory Number:	21 CFR 892.2050
Product Code:	LLZ
Reference Device:	Viewpoint 6 (K203677)
510(k) Submitter/Holder:	GE Medical Systems Ultrasound and Primary Care Diagnostics
Classification Regulation:	21 CFR 892.2050
Product Code:	LLZ

Device Description:

TeleScan™ is used by trained medical professionals, including radiologists, sonographers, technologists, and clinicians, and may provide information to be used for screening and diagnostic procedures. These individuals are referred to as Healthcare Workers (HCWs) for the purposes of this submission.

Similar to tele-radiology solutions, TeleScan™ allows remote, qualified radiologists and clinicians to provide a diagnosis remotely. TeleScan™ receives ultrasound DICOM images transmitted from legally marketed ultrasound machines and displays images. This includes videos (cineloops), diagnostics tools for annotation, and a simplified workflow for report creation. TeleScan™ is compatible with ultrasound images acquired by appropriately trained healthcare professionals in medical facilities.

The software provides the Sonographer tools to display patient measurements and observations. The application also calculates gestational age and growth percentiles based on

measurements of anatomical structures. Through a diagnostics function, the estimated due date and estimated fetal weight is calculated.

The report is prepared for further interpretation by medical professionals licensed to sign diagnostic reports such as physicians, specialists, and nurse practitioners. For the purposes of this submission, these individuals are referred to as “Physicians”.

TeleScan™ is offered as software as a service (SaaS) and complies with digital health and data related laws, including but not limited to HIPAA.

Indications for Use:
TeleScan™ is a software application that is intended for use in receiving, processing, manipulating, displaying, printing, and archiving ultrasound medical images and data. Images and data can be stored, communicated, and displayed within the system or across computer systems. TeleScan™ provides various image processing and measurement tools to facilitate the interpretation of ultrasound DICOM medical images and enable diagnosis.

TeleScan™ is used by appropriately trained healthcare professionals, including radiologists, sonographers, technologists, and clinicians, in a medical facility. TeleScan™ may provide information to be used for screening and diagnostic procedures. TeleScan™ allows remote qualified radiologists and clinicians to provide a diagnosis remotely.

Substantial Equivalence

TeleScan™, Unifi Workspace (predicate device), and Viewpoint 6 (reference device), have the same intended use. The proposed device has similar technological characteristics, application features, operational use as the predicate and reference devices as noted in the comparison matrix below. Specifically, the proposed device is intended to receive, process, manipulate, display, print, and archive ultrasound (US) images which is the same as the predicate device. The technological characteristics of OB/Gyn and fetal measurements, annotation tools, and report features are the same as the Viewpoint 6 reference device. The differences between TeleScan™ and the predicate and reference devices do not raise any questions of safety and effectiveness.

Table 5-A: Substantial Equivalence Comparison

	(Primary Predicate) **Unifi Workspace** K190694	**(Reference Device)** **Viewpoint 6** K203677	**(Proposed Device)** **TeleScan™** K220767
Indications for Use	Unifi Workspace is a software application that is intended for use in receiving, processing, manipulating, displaying, printing, and archiving mammography images as well as other medical images and data (e.g., US and MR). Images and data can be stored, communicated, and displayed within the system or across computer systems. Unifi Workspace provides various image processing and measurement tools to facilitate the interpretation of mammography x-ray, breast tomosynthesis, and other multimodality DICOM medical images and enable diagnosis. Lossy compressed mammographic images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a legally marketed monitor that meets technical specifications reviewed and accepted by the FDA. Unifi Workspace is typically used by trained professionals, including radiologists, oncologists, surgeons, technologists, and clinicians, and may provide information to be used for screening and diagnostic procedures.	Viewpoint 6 is intended to be used in medical practices and in clinical departments and serves the purposes of diagnostic interpretation of images, electronic documentation of examinations in the form of text and images, and generation of medical reports primarily for diagnostic ultrasound. Viewpoint 6 provides the user the ability to include images, drawings, and charts into medical reports. Viewpoint 6 is designed to accept, transfer, display, calculate, store, and process medical images and data, and enables the user to measure and annotate the images. The medical images, which Viewpoint 6 displays to the user, can be used for diagnostic purposes. Viewpoint 6 is intended for professional use only. Viewpoint 6 is not intended to be used as an automated diagnosis system. Viewpoint 6 is not intended to operate medical devices in surgery related procedures.	TeleScan™ is a software application that is intended for use in receiving, processing, manipulating, displaying, printing, and archiving ultrasound medical images and data. Images and data can be stored, communicated, and displayed within the system or across computer systems. TeleScan™ provides various image processing and measurement tools to facilitate the interpretation of ultrasound DICOM medical images and enable diagnosis. TeleScan™ is used by appropriately trained healthcare professionals, including radiologists, sonographers, technologists, and clinicians, in a medical facility. TeleScan™ may provide information to be used for screening and diagnostic procedures. TeleScan™ allows remote qualified radiologists and

	(Primary Predicate) **Unifi Workspace** K190694	(Reference Device) **Viewpoint 6** K203677	(Proposed Device) **TeleScan™** K220767
			clinicians to provide a diagnosis remotely.
Regulatory Number:/Common Name	21 CFR 892.2050 (Medical image management and processing system)	21 CFR 892.2050 (Medical image management and processing system)	Same
Device Class	II	II	Same
Software Level of Concern	Moderate	Moderate	Same
Method of Use	Multi-modality workstation that provides various image processing and measurement tools to facilitate diagnostic and non-diagnostic viewing capabilities.	Software that provides various image processing and measurement tools to facilitate diagnostic viewing capabilities of ultrasound images, as well as electronic documentation of exams and generation of medical reports.	Software that provides various image processing and measurement tools to facilitate diagnostic and non-diagnostic viewing capabilities of ultrasound images, as well as electronic documentation of exams and generation of medical reports.
Mechanism of Action	Viewing, patient management, study data management	Viewing, patient management, study data management	Same
Operating System	Windows 10	Windows	Similar; works on MacOS (Big Sur & Monterey and beyond) and Windows OS (Windows 10, Windows 11 and beyond)
System Access	Local Application	Local application and a cloud-based system	Cloud-based system
Modalities supported on display	US, MR, MG, BTO, DR, CR, SC, CT, and other DICOM formats	US	US
DICOM Input for Medical Images	Accept and display any valid DICOM-standard object	Accept and display any valid DICOM-standard object	Accept and display any valid DICOM-standard object
Tomosynthesis image display	Support for all available BTO images	No, limited to Ultrasound	No, limited to Ultrasound
CAD Support	Yes	No, limited to Ultrasound	No, limited to Ultrasound

	(Primary Predicate) **Unifi Workspace** K190694	**(Reference Device)** **Viewpoint 6** K203677	**(Proposed Device)** **TeleScan™** K220767
Image viewing and manipulation tools	Window/Level, Pan, Zoom, Invert, Flip, Rotate, View/Create, Annotations, Scrolling, Cine, Measurement, Magnify, Link Data Sets, Size Mode Control, Toggle Study/Patient Overlays, Reset, Display text Overlays, MIP, Intelligent Roaming	Window/Level, Pan, Zoom, Rotate, View/Create, Annotations, Scrolling, Cine, Measurement, Magnify, Link Data Sets, Toggle Study/Patient Overlays, Reset, Display Text Overlays, Ellipse Tool, Arrow, Brightness, Impression Box	Window/Level, Pan, Zoom, View/Create, Annotations, Scrolling, Cine, Measurement, Magnify, Link Data Sets, Toggle Study/Patient Overlays, Reset, Display Text Overlays, Ellipse Tool, Arrow, Brightness, Impression Box
Gestational age based on measurements of anatomical structures	No	Yes	Yes
Growth percentiles based on measurements of anatomical structures	No	Yes	Yes
Estimated due date based on measurements of anatomical structures	No	Yes	Yes
Estimated fetal weight based on measurements of anatomical structures	No	Yes	Yes
Enables quick diagnostic reporting with standardized terminology	Yes	Yes	Yes
Ob/Gyn and fetal measurements	No	Yes	Same as reference device
Report Capabilities	Yes	Yes	Yes
Application	Yes	Yes	Same

	(Primary Predicate) **Unifi Workspace** K190694	(Reference Device) **Viewpoint 6** K203677	(Proposed Device) **TeleScan™** K220767
Synchronization Support			

Summary of Performance Testing
BB Imaging successfully performed system design control verification and validation tests for TeleScan™, which are summarized in accordance with FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (issued May 11, 2005) based on a moderate level of concern. Substantial equivalence has been demonstrated by non-clinical testing. Additional bench testing, including functional testing and usability testing, was also performed on TeleScan™. The performance testing showed that the overall system demonstrated equivalent performance and equivalent safety and effectiveness as the predicate (Unifi Workspace, K190694) for specific application features.

No clinical studies have been performed to support substantial equivalence.

Conclusion:
In conclusion, BB Imaging has established substantial equivalence of the subject TeleScan™ to the predicate device. No new issues of safety or effectiveness are introduced by using this device. The intended use, technological characteristics, and operational use are substantially equivalent to the predicate device.