BB Imaging
℅ Prithul Bom
Most Repsonsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, MN 55114

Re: K233634 December 12, 2023
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: November 10, 2023
Received: November 13, 2023

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 (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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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
Assistant Director
Imaging Software Team
DHT8B: Division of Radiologic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233634

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 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.

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

1 Submitter Information

Submitter: BB Imaging

Address: 9701 Brodie Lane, Suite 200
Austin Texas 78748

Website: https://www.bbimaging.net/telescan

Phone Number: 844-766-6111

Contact Person: Britt Einspahr, Manager of Quality Systems and Regulatory Affairs

Date of Summary: December 8, 2023

2 Device Information

Name of Device:	TeleScan®
Common or Usual Name:	Medical Image Management and Processing System
Device Classification Name:	Radiological Image Processing System
Regulatory Classification:	Class II
Regulation Number:	21 CFR 892.2050
Classification Product Code:	LLZ
Panel:	Radiology
Type of 510(k) Submission:	Special
Reason for Submission:	Design Update

3 Predicate Information

Predicate: TeleScan®

Predicate 510(k): K220767

4 Device Description

TeleScan® is used by trained medical professionals, including radiologists, sonographers, technologists, and clinicians, and may provide information to be used for diagnostic procedures. These individuals are referred to as healthcare workers for the purposes of this submission.

Like tele-radiology solutions, TeleScan® allows remotely located qualified radiologists and clinicians to provide a diagnosis. TeleScan® receives DICOM images transmitted from legally marketed ultrasound machines and displays the patient images. This includes cineloops (videos), 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.

TeleScan® software provides sonographers with tools to display patient measurements and observations (annotations). The application displays calculated gestational age and growth percentiles based on measurements of anatomical structures. Through a diagnostics function, the estimated due date and estimated fetal weight are calculated.

A draft patient report is prepared for further interpretation by medical professionals licensed to sign diagnostic reports, such as physicians, specialists, and nurse practitioners (providers).

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

5 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 diagnostic procedures. TeleScan® allows remote qualified radiologists and clinicians to provide a diagnosis remotely.

6 Comparison with Predicate and Technological Characteristics

Characteristic	Predicate – TeleScan® K220767	TeleScan® K233634
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.	Same (With "screening" removed per FDA pre-submission guidance.)
Regulatory Number & Common Name	21 CFR 892.2050 Medical image management and processing system	Same
Device Class	Class II	Same
Software Level of Concern	Moderate	Same
Method of Use	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.	Same
Mechanism of Action	Viewing, patient management, study data management	Same
Operating System	Similar; works on MacOS (Big Sur & Monterey and beyond) and Windows OS (Windows 10, Windows 11 and beyond)	Same
System Access	Cloud-based system	Same
DICOM Input for Medical Images	Accept and display any valid DICOM-standard object	Same
Image viewing and manipulation tools	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	Same
Gestational age based on measurements of anatomical structures	Yes	Same

Characteristic	Predicate – TeleScan® K220767	TeleScan® with 2.0 Software
Growth percentiles based on measurements of anatomical structures	Yes	Same
Estimated due date based on measurements of anatomical structures	Yes	Same
Estimated fetal weight based on measurements of anatomical structures	Yes	Same
Enables quick diagnostic reporting with standardized terminology	Yes	Same
Ob/Gyn and fetal measurements	Yes	Same
Report Capabilities	Yes	Same
Application Synchronization Support	Yes	Same
DICOM Standard Applied and Documented in Labeling	Yes	Same
DICOM Specification	Current DICOM Edition (DICOM 3.0 2023b and prior)	Same
Image Format	PNG	JPG
Image Quality Decisions	Under the practice of medicine	Same
Responsibility for Ensuring Sufficient Image Quality to Achieve Diagnostically Acceptable Goal	Responsible physician	Same
Image Preservation and Archiving	Maintained in same format and quality as reviewed by physician for diagnosis	Same

7 Nonclinical Testing

The performance characteristics of TeleScan® with the 2.0 software update were evaluated, verified, and validated for demonstration of performance and data for determination of substantial equivalence. The FDA's guidance for Industry and FDA Staff "Guidance for the Content of Premarket Submissions for Software Contained on Medical Devices" was referenced and followed. The non-clinical evaluations and data summaries are presented in Section 15 for verification and validation activities with a bullet point overview provided below:

- **Sonographer Evaluation** – An evaluation was conducted with a large group of prenatal sonographers to assess a range of ultrasound JPG output quality settings to provide data for assessment and establish a specification and lower limit for safe and effective use with TeleScan®,
- **Physician Evaluation** – A performance validation was performed with a large group of physicians to validate the performance, diagnostic acceptability, and physician diagnosis process acceptability of the determined ultrasound output settings, TeleScan® JPG usage specification, and lower limit to demonstrate and support the safety and effectiveness of the proposed design update,
- **Design Verification and Validation** – Design verification and validation was performed to demonstrate the functionality of the TeleScan with 2.0 software feature for monitoring the ultrasound output quality factor setting to ensure that it remains at or above the TeleScan® specification or otherwise notifies users with a pop-up message of the lower than expected (out of spec) settings with labeling applied to all associated images until the ultrasound settings issue is resolved. This control ensures that ultrasound output settings are correctly set and maintained and that any accidental or inadvertent change below specification ensures users are made aware to correct the setting with images labeled with messaging until the issue is resolved, and
- **Human Factors Validation** – A human factors evaluation was performed with users to review the clarity and adequacy of wording uses for image quality information that is displayed, the pop-up notification that occurs with any below specification image received by TeleScan from the ultrasound, and the permanent messaging added to images that are received by TeleScan® that are below the stated specification.

Software design, development, verification, human factors, and validation activities followed all applicable guidelines and standards throughout the software development process, including:

- FDA Guidance for Industry and FDA Staff Guidance for the content of premarket submissions for software contained in medical devices (May 11, 2005)
- EN ISO 14971:2019 Application of risk management to medical devices
- IEC 62304:2006 Medical device software - Software life cycle processes
- EN 62366-1:2015/A1:2020 Medical Device Part I – Application of the Usability Engineering to Medical Devices
- IEC 82304-1:2016 Health Software – Part I General Requirements for Product Safety

The results of the evaluations demonstrate the equivalency of the proposed TeleScan® with 2.0 software update for JPG image type use with a specification, lower limit, and image quality monitoring with no differences in performance as reported with data provided by the physician user group. The evaluations and resulting data support that safety and effectiveness are maintained with the proposed TeleScan with the 2.0 software. The proposed update has been fully documented through internal design control processes with design reviews, risk analyses review and update, design verification, design validation evaluations and data, and design history record updates. The evaluations were performed through sequential and side-by-side image reviews by healthcare professionals in the same method and approached used for the predicate 510k data, submission, and clearance. The validation data demonstrates that TeleScan® with 2.0 software continues to meet and satisfy user requirements and the indications for use statement.

8 Clinical Testing

Testing with patients was not necessary for demonstration of the safety and effectiveness of this update.

9 Performance Summary

Performance testing, data, evaluations, and results, including provisions for risk management, demonstrated conformity to pre-established acceptance criteria, substantial equivalence to the predicate device, and the continued safety and effectiveness of TeleScan® with the 2.0 software and design update.

10 Conclusion

TeleScan® with 2.0 software performs as well as the predicate device. The validations performed and the resulting data support that TeleScan® continues to perform safely and effectively in accordance with its intended use.
No new issues of safety or effectiveness are raised by the design update. The same application features, operational use, and diagnostic and diagnosis performance are maintained. The same functionality is carried forward for receiving, processing, manipulating, displaying, printing, and archiving ultrasound (US) images with tools for OB/Gyn and fetal measurement, annotation, and report authoring.

11 Substantial Equivalence

TeleScan® with 2.0 software is substantially equivalent to the predicate version of the device. TeleScan® with 2.0 software continues to perform safely and effectively for its intended use.