Gleamer
℅ Antoine Tournier
Head of Quality & Regulatory
5 avenue du Général de Gaulle
Saint Mandé, 94160
FRANCE

March 1, 2022

Re: K212365
Trade/Device Name: BoneView
Regulation Number: 21 CFR 892.2090
Regulation Name: Radiological computer assisted detection and diagnosis software
Regulatory Class: Class II
Product Code: QBS
Dated: January 28, 2022
Received: January 31, 2022

Dear Antoine Tournier:

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,

Jessica Lamb, Ph.D.
Assistant Director
Mammography Ultrasound and Imaging Software Branch
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)*

K212365

Device Name

BoneView

Indications for Use *(Describe)*

BoneView is intended to analyze radiographs using machine learning techniques to identify and highlight fractures during the review of radiographs of:

Study Type (Anatomical Area of Interest)	Compatible Radiographic View(s)
Ankle	Frontal, Lateral, Oblique
Foot	Frontal, Lateral, Oblique
Knee	Frontal, Lateral
Tibia/Fibula	Frontal, Lateral
Femur	Frontal, Lateral
Wrist	Frontal, Lateral, Oblique
Hand	Frontal, Oblique
Elbow	Frontal, Lateral
Forearm	Frontal, Lateral
Humerus	Frontal, Lateral
Shoulder	Frontal, Lateral, Axillary
Clavicle	Frontal
Pelvis	Frontal
Hip	Frontal, Frog Leg Lateral
Ribs	Frontal Chest, Rib series
Thoracic Spine	Frontal, Lateral
Lumbosacral Spine	Frontal, Lateral

BoneView is intended for use as a concurrent reading aid during the interpretations of radiographs. BoneView is for prescription use only and is indicated for adults only.

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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Date prepared: 01st, March 2022

K212365

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for BoneView is provided below.

1. Submitter

Submitter	**GLEAMER SAS** 5, avenue du Général de Gaulle 94160 Saint-Mandé - FRANCE
Primary Contact Person	**Antoine Tournier** Head of Quality & Regulatory Affairs Tel: 0033 6 15 81 23 45 Email: antoine.tournier@gleamer.ai
Secondary Contact Person	**Christian Allouche** CEO Tel: 0033 6 58 53 70 46 Email: christian@gleamer.ai

2. Device

Trade Name	BoneView
510(k) reference	K212365
Common Name	Radiological computer assisted detection/diagnosis software for fracture
Regulation	21 CFR 892.2090
Product Code	QBS
Classification	Class II

3. Predicate Device

Predicate Device	Imagen Technologies, Inc - FractureDetect
510(k) reference	K193417

4. Device Description

BoneView is intended to analyze radiographs using machine learning techniques to identify and highlight fractures during the review of radiographs.

BoneView can be deployed on-premises or on cloud and be connected to several computing platforms and X-ray imaging platforms such as X-ray radiographic systems, or PACS. More precisely, BoneView can be deployed:

- In the cloud with a PACS as the DICOM Source
- On-premises with a PACS as the DICOM Source
- On-premises with an X-ray system as the DICOM Source

It is important to note that no matter the deployment mode that is chosen for BoneView, the overall principle of use of BoneView and its user interface remain the same; only the place where BoneView is housed, and the DICOM Source/DICOM Destination with which BoneView communicates, may vary. Below is a description of the data flow.

After the acquisition of the radiographs on the patient and their storage in the DICOM Source, the radiographs are automatically received by BoneView from the user's DICOM Source through an intermediate DICOM node (for example, a specific Gateway, or a dedicated API). The DICOM Source can be the user's image storage system (for example, the Picture Archiving and Communication System, or PACS), or other radiological equipment (for example X-ray systems).

Once received by BoneView, the radiographs are automatically processed by the AI algorithm to identify regions of interest. Based on the processing result, BoneView generates result files in DICOM format. These result files consist of a summary table and result images (annotations on a copy of the original images or annotations to be toggled on/off). BoneView does not alter the original images, nor does it change the order of original images or delete any image from the DICOM Source.

Once available, the result files are sent by BoneView to the DICOM Destination through the same intermediate DICOM node. Similar to the DICOM Source, the DICOM Destination can be the user's image storage system (for example, the Picture Archiving and Communication System, or PACS), or other radiological equipment (for example X-ray systems). The DICOM Source and the DICOM Destination are not necessarily identical.

The DICOM Destination can be used to visualize the result files provided by BoneView or to transfer the results to another DICOM host for visualization. The users are then able to use them as a concurrent reading aid to provide their diagnosis.

The general layout of images processed by BoneView is comprising:

① The "summary table" – it is a first image that is derived from the detected regions of interest in the following result images and that displays the results of the overall study along with the Gleamer – BoneView logo. This summary can be configured to be present or not.

② The result images – they are provided for all the images that were processed by BoneView and contain:

- Around the Regions of Interest (if any), a rectangle with a solid or dotted line depending on the confidence of the algorithm (see below)
- Around the entire image, a white frame showing that the images were processed by BoneView
- Below the image:
    - The Gleamer – BoneView logo
    - The number of Regions of interest that are displayed in the result image
    - (if any) The caution message if it was identified that the image was not part of the indication for use of BoneView

The training of BoneView was performed on a training dataset of 44,649 radiographs, representing 151,096 images (52.4% of males, with age: range [0 – 109]; mean 42.4 +/- 24.6) for all anatomical areas of interest in the Indications for Use and from various manufacturers. BoneView has been designed to solve the problem of missed fractures including subtle fractures, and thus detects fractures with a high sensitivity. In this regard, the display of findings is triggered by a "high-sensitivity operating point" (DOUBT FRACT) that will enable the display of a dotted-line bounding box around the region of interest. Additionally, the users need to be confident that when BoneView identifies a fracture, it is actually a fracture. In this regard, an additional information is introduced to the user with a "high-specificity operating point" (FRACT).

These two operating points are implemented in the User Interface as follow:

- **Dotted-line Bounding Box**: suspicious area / subtle fracture (when the level of confidence of the AI algorithm associated with the finding is above "high-sensitivity

operating point" and below "high-specificity operating point") displayed as a dotted bounding box around the area of interest

- **Solid-line Bounding Box**: definite or unequivocal fractures (when the level of confidence of the AI algorithm associated with the finding is above "high-specificity operating point") displayed as a solid bounding box around the area of interest

BoneView can provide 4 levels of results:

- **FRACT**: BoneView identified at least one solid-line bounding box on the result images,
- **DOUBT FRACT**: BoneView did not identify any solid-line bounding box on the result images but it identified at least one dotted-line bounding box in the result images,
- **NO FRACT**: BoneView did not identify any bounding box at all in the result images,
- **NOT AVAILABLE**: BoneView identified that the original images are out of its Indications for Use

5. Intended use/Indications for use

BoneView is intended to analyze radiographs using machine learning techniques to identify and highlight fractures during the review of radiographs of:

Study Type (Anatomical Area of Interest)	Compatible Radiographic View(s)
Ankle	Frontal, Lateral, Oblique
Foot	Frontal, Lateral, Oblique
Knee	Frontal, Lateral
Tibia/Fibula	Frontal, Lateral
Femur	Frontal, Lateral
Wrist	Frontal, Lateral, Oblique
Hand	Frontal, Oblique
Elbow	Frontal, Lateral
Forearm	Frontal, Lateral
Humerus	Frontal, Lateral
Shoulder	Frontal, Lateral, Axillary
Clavicle	Frontal
Pelvis	Frontal
Hip	Frontal, Frog Leg Lateral
Ribs	Frontal Chest, Rib series
Thoracic Spine	Frontal, Lateral
Lumbosacral Spine	Frontal, Lateral

BoneView is intended for use as a concurrent reading aid during the interpretations of radiographs. BoneView is for prescription use only and is indicated for adults only.

6. Substantial equivalence

Features and Characteristics	**Subject Device** Gleamer BoneView	**Predicate Device** Imagen Technologies Inc. FractureDetect
Regulation Information		
Regulation Number/Name	21 CFR 892.2090 / Radiological Computer Assisted Detection and Diagnosis Software for Fracture	Same
Regulation Description	A radiological computer assisted detection and diagnostic software for suspected fracture is an image processing device intended to aid in the detection, localization, and/or characterization of fracture on acquired medical images (e.g. radiography, MR, CT). The device detects, identifies, and/or characterizes fracture based on features or information extracted from images, and may provide information about the presence, location, and/or characteristics of the fracture to the user. Primary diagnostic and patient management decisions are made by the clinical user.	Same
Intended Use	The device is intended to aid in the detection, localization, and characterization of fractures on acquired medical images (per 21 CFR 892.2090 Radiological Computer Assisted Detection and Diagnosis Software For Fracture).	Same
Indications for Use		
Image Modality	2D Xray Images	Same

Features and Characteristics	Subject Device Gleamer BoneView	Predicate Device Imagen Technologies Inc. FractureDetect
Clinical Finding and Clinical Output	Fracture To inform the primary diagnostic and patient management decisions that are made by the clinical user.	Same
Mode of action	Image processing software using machine learning to aid in identifying and highlighting fractures during the review of radiographs.	Same
Anatomic Areas of Interest and Patient Population	For adults (greater than 21 years of age): • Ankle • Foot • Knee • Tibia/Fibula • Femur • Wrist • Hand • Elbow • Forearm • Humerus • Shoulder • Clavicle • Pelvis • Hip • Ribs • Thoracic Spine • Lumbosacral Spine	For adults (greater than 21 years of age): • Ankle • Clavicle • Elbow • Femur • Forearm • Hip • Humerus • Knee • Pelvis • Shoulder • Tibia / Fibula • Wrist
Intended Users	The intended users of BoneView are clinicians with the authority to diagnose fractures in various settings including primary care (e. g., family practice, internal medicine), emergency medicine, urgent care, and specialty care (e. g. orthopedics), as well as radiologists who review radiographs across settings.	Same
Software and Technical Information		
Machine Learning Methodology	Supervised Deep Learning	Same

Features and Characteristics	Subject Device Gleamer BoneView	Predicate Device Imagen Technologies Inc. FractureDetect
Image Source	DICOM Source (e.g., imaging device, intermediate DICOM node, PACS system, etc.)	Same
Image Viewing	PACS system Image annotations made on copy of original image or image annotations toggled on/off	PACS system Image annotations toggled on/off
Deployment Platform	Deployment on-premises or on cloud and connection to several computing platforms and X-ray imaging platforms such as X-ray radiographic systems, or PACS	Secure local processing and delivery of DICOM images
Privacy	HIPAA Compliant	Same
Software Level of Concern	Moderate	Same

7. Performance data

7.1. Biocompatibility Testing

As a standalone software, BoneView has no direct or indirect patient or user contacting components. Therefore, biocompatibility information is not required for this device.

7.2. Software Verification and Validation Testing

BoneView is a standalone software that is considered a moderate level of concern as per the guidance document from the FDA: “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”. Indeed, a failure or latent design flaw of BoneView could directly result in minor injury to the patient or operator.

Consequently, software verification and validation testing were conducted and documented as per the requirements of the abovementioned FDA guidance document for a moderate level of concern device.

7.3. Electrical safety and Electromagnetic compatibility Testing

As a standalone software, BoneView is not subject to electromagnetic compatibility or electrical safety testing activities. Therefore, Electrical safety and Electromagnetic compatibility information is not required for this device.

7.4. Bench Testing

Gleamer performed a standalone performance testing on a dataset of 8,918 radiographs (47.2% of males, with age: range [21 – 113]; mean 52.5 +/- 19.8) for all anatomical areas of interest in the Indications for Use and from various manufacturers (Agfa, Fujifilm, GE Healthcare, Kodak, Konica Minolta, Philips, Primax, Samsung, Siemens). This dataset was independent of the data used for model training, tuning, and establishment of device operating points.

The results of the standalone testing demonstrated that BoneView detects fractures in radiographs with high sensitivity and high specificity:

Specificity (with 95% Clopper-Pearson CI) and Sensitivity (with 95% Clopper-Pearson CI) of BoneView at the examination-level at the high-sensitivity operating point and high-specificity operating point on the merged datasets

	High-sensitivity operating point		**High-specificity operating point**	
Standalone Performance	**Specificity – 95% Clopper-Pearson CI**	**Sensitivity – 95% Clopper-Pearson CI**	**Specificity – 95% Clopper-Pearson CI**	**Sensitivity – 95% Clopper-Pearson CI**
Global n(positive)= 3,886 n(negative)= 5,032	0.811 [0.8 - 0.821]	**0.928 [0.919 - 0.936]**	**0.932 [0.925 - 0.939]**	0.841 [0.829 - 0.853]

Specificity (with 95% Clopper-Pearson CI) and Sensitivity (with 95% Clopper-Pearson CI) of BoneView at the examination-level for the subgroup analysis of anatomical areas of interest at the high-sensitivity operating point and high-specificity operating point on the merged datasets

	High-sensitivity operating point DOUBT FRACT		**High-specificity operating point FRACT**	
Anatomical Areas of Interest	**Specificity – 95% Clopper-Pearson CI**	**Sensitivity – 95% Clopper-Pearson CI**	**Specificity – 95% Clopper-Pearson CI**	**Sensitivity – 95% Clopper-Pearson CI**
Ankle n(positive)= 378 n(negative)= 805	0.784 [0.754 - 0.812]	**0.95 [0.923 - 0.969]**	**0.897 [0.874 - 0.917]**	0.899 [0.865 - 0.928]
Clavicle n(positive)= 147 n(negative)= 255	0.757 [0.699 - 0.808]	**0.905 [0.845 - 0.947]**	**0.929 [0.891 - 0.958]**	0.83 [0.759 - 0.887]

	High-sensitivity operating point DOUBT FRACT		High-specificity operating point FRACT	
Anatomical Areas of Interest	**Specificity – 95% Clopper-Pearson CI**	**Sensitivity – 95% Clopper-Pearson CI**	**Specificity – 95% Clopper-Pearson CI**	**Sensitivity – 95% Clopper-Pearson CI**
Elbow n(positive)= 145 n(negative)= 227	0.718 [0.655 - 0.776]	**0.924 [0.868 - 0.962]**	**0.899 [0.852 - 0.935]**	0.531 [0.446 - 0.614]
Femur n(positive)= 63 n(negative)= 161	0.733 [0.658 - 0.799]	**0.937 [0.845 - 0.982]**	**0.944 [0.897 - 0.974]**	0.825 [0.709 - 0.909]
Foot n(positive)= 985 n(negative)= 1,097	0.793 [0.768 - 0.817]	**0.934 [0.917 - 0.949]**	**0.924 [0.907 - 0.939]**	0.874 [0.852 - 0.894]
Forearm n(positive)= 94 n(negative)= 102	0.676 [0.577 - 0.766]	**0.989 [0.942 - 1.0]**	**0.912 [0.839 - 0.959]**	0.851 [0.763 - 0.916]
Hand n(positive)= 1,168 n(negative)= 1,003	0.809 [0.783 - 0.832]	**0.966 [0.954 - 0.975]**	**0.917 [0.898 - 0.934]**	0.915 [0.898 - 0.931]
Hip n(positive)= 145 n(negative)= 235	0.77 [0.711 - 0.822]	**0.938 [0.885 - 0.971]**	**0.953 [0.918 - 0.976]**	0.793 [0.718 - 0.856]
Humerus n(positive)= 114 n(negative)= 175	0.731 [0.659 - 0.796]	**0.904 [0.834 - 0.951]**	**0.92 [0.869 - 0.956]**	0.833 [0.752 - 0.897]
Knee n(positive)= 128 n(negative)= 1,045	0.889 [0.868 - 0.907]	**0.891 [0.823 - 0.939]**	**0.975 [0.964 - 0.984]**	0.797 [0.717 - 0.863]
Lumbosacral Spine n(positive)= 125 n(negative)= 209	0.737 [0.672 - 0.795]	**0.776 [0.693 - 0.846]**	**0.947 [0.908 - 0.973]**	0.6 [0.509 - 0.687]
Pelvis n(positive)= 230 n(negative)= 479	0.745 [0.704 - 0.784]	**0.887 [0.839 - 0.925]**	**0.939 [0.914 - 0.959]**	0.743 [0.682 - 0.799]
Ribs n(positive)= 252 n(negative)= 95	0.684 [0.581 - 0.776]	**0.753 [0.7 - 0.802]**	**0.926 [0.854 - 0.97]**	0.488 [0.425 - 0.552]
Shoulder n(positive)= 255 n(negative)= 586	0.782 [0.746 - 0.814]	**0.929 [0.891 - 0.958]**	**0.947 [0.926 - 0.964]**	0.851 [0.801 - 0.892]

	High-sensitivity operating point DOUBT FRACT		High-specificity operating point FRACT	
Anatomical Areas of Interest	**Specificity – 95% Clopper-Pearson CI**	**Sensitivity – 95% Clopper-Pearson CI**	**Specificity – 95% Clopper-Pearson CI**	**Sensitivity – 95% Clopper-Pearson CI**
Thoracic Spine n(positive)= 74 n(negative)= 105	0.676 [0.578 - 0.764]	**0.878 [0.782 - 0.943]**	**0.905 [0.832 - 0.953]**	0.689 [0.571 - 0.792]
Tibia/Fibula n(positive)= 72 n(negative)= 184	0.712 [0.641 - 0.776]	**0.972 [0.903 - 0.997]**	**0.815 [0.751 - 0.869]**	0.931 [0.845 - 0.977]
Wrist n(positive)= 573 n(negative)= 502	0.771 [0.732 - 0.807]	**0.97 [0.953 - 0.983]**	**0.892 [0.862 - 0.918]**	0.934 [0.91 - 0.953]

Additionally, the performance of BoneView was validated for potential confounders including weight-bearing and non-weight bearing bone fractures and different X-ray system manufacturers.

7.5. Animal Studies

No animal studies were conducted in support of the 510(k) submission of BoneView.

7.6. Clinical studies

Gleamer conducted a fully-crossed multiple reader, multiple case (MRMC) retrospective reader study to determine the impact of BoneView on reader performance in diagnosing fractures. The primary objective of the study was to determine whether the diagnostic accuracy of readers aided by BoneView is superior to the diagnostic accuracy of readers unaided by BoneView as determined by the Specificity/Sensitivity pair (primary endpoint).

The clinical validation study design was the following:

- 24 clinical readers each evaluated a dataset of 480 cases (31.9% of males, with age: range [21 – 93]; mean 59.2 +/- 16.4) in BoneView's Indications for Use and from various manufacturers (GE Healthcare, Kodak, Konica Minolta, Philips, Samsung) under both Aided and Unaided conditions.
- This dataset was independent of the data used for model training, tuning, and establishment of device operating points.
- Each case had been previously evaluated by a panel of three U.S. board-certified radiologists who assigned a ground truth label indicating the presence or absence of a fracture and its location.

- Cases are from all the anatomical areas of interest included in BoneView's Indications for Use.
- The MRMC study consisted of two independent reading sessions separated by a washout period of at least one month in order to avoid memory bias.
- For each case, each reader was required to provide a determination of the presence or absence of a fracture and provide its location.

The results of the study found that the diagnostic accuracy of readers in the intended use population is superior when aided by BoneView than when unaided by BoneView, as measured at the task of fracture detection using the Specificity/Sensitivity pair.

In particular, the study results demonstrated:

- Reader specificity improved significantly from 0.906 (95% bootstrap CI: 0.898-0.913) to 0.956 (95% bootstrap CI: 0.951-0.960): **+5% increase of the Specificity**
- Reader sensitivity improved significantly from 0.648 (95% bootstrap CI: 0.640-0.656) to 0.752 (95% bootstrap CI: 0.745-0.759): **+10.4% increase of the Sensitivity**

Additionally, subgroup analysis was carried out by anatomical areas of interest, listed in the Indications for Use. The subgroup analysis found that the Sensitivity and Specificity were higher for Aided reads versus Unaided reads for all of the anatomical areas of interest.

8. Conclusion

BoneView is as safe and effective as the predicate device.

BoneView and the predicate device are both computer-assisted detection and diagnostic devices that take radiographs in DICOM format and use machine learning techniques to identify and highlight fractures.

The overall design of the software and the basic functionality that it provides to the end user are the same. The minor differences between subject and predicate device in indications do not alter the intended use of the device and do not raise new or different questions regarding its safety and effectiveness when used as labeled.

The results of performance and clinical studies demonstrate that the subject device performs in accordance with specifications and meets user needs and intended use and that BoneView can be found to be substantially equivalent to the predicate device.