Gleamer SAS
Antoine Tournier
Chief Compliance Officer
47bis, rue des Vinaigriers
PARIS, 75010
FRANCE

February 5, 2025

Re: K241593
Trade/Device Name: BoneMetrics (US)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: January 7, 2025
Received: January 7, 2025

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 (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.

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, PhD
Assistant Director
Imaging Software Team
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)*

K241593

Device Name

BoneMetrics (US)

Indications for Use *(Describe)*

BoneMetrics US is a fully automated radiological image processing software device intended to aid users in the measurement of Cobb angles on frontal spine radiographs of individuals of at least 4 years old for patients with suspected or present spinal deformities, such as scoliosis. It should not be used instead of full patient evaluation or solely relied upon to make or confirm a diagnosis. The software device is to be used by healthcare professionals trained in radiology.

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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Date prepared: February 4th, 2025

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

1. Submitter

Submitter	GLEAMER SAS 47bis, rue des Vinaigriers 75010, Paris 10, FRANCE
Primary Contact Person	Antoine Tournier Chief Compliance Officer Tel: 0033 6 15 81 23 45 Email: antoine.tournier@gleamer.ai Alternate email: qara@gleamer.ai

2. Device

Trade Name	BoneMetrics (US)
510(k) reference	K241593
Common Name	Automated Radiological Image Processing Software
Regulation	21 CFR 892.2050
Product Code	QIH
Classification	Class II

3. Predicate Device

Predicate Device	IB Lab LAMA
510(k) Reference	K223646

4. Device Description

BoneMetrics US is intended to analyze radiographs using machine learning techniques to provide fully automated measurements of cobb angles during the review of frontal spine radiographs.

BoneMetrics US can be deployed on cloud and be connected to several computing platforms and X-ray imaging platforms such as radiographic systems, or PACS. More precisely, BoneMetrics US can be deployed in the cloud connected to a DICOM Source/Destination with a DICOM Viewer, i.e. a PACS.

After the acquisition of the radiographs on the patient and their storage in the DICOM Source, the radiographs are automatically received by BoneMetrics US from the user's DICOM Source through intermediate DICOM node(s) (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 BoneMetrics US, the radiographs are automatically processed by the AI algorithm without requiring any user inputs. The algorithm identifies the keypoints corresponding to the corners of all the vertebras that are seen on the images and calculates all possible angles between vertebras. Only Cobb Angles that are above 7° are retained. Based on the processing result, BoneMetrics US generates result files in DICOM format. These result files consist of annotated images with the measurements plotted on a copy of all images (as an overlay) and angle values displayed in degrees. BoneMetrics US 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 BoneMetrics US to the DICOM Destination through the same intermediate DICOM node(s). 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 BoneMetrics US 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 displayed result for the BoneMetrics US is a summary in a unique Secondary Capture with the following information:

- The image with the angle(s) in degree drawn as an overlay (if any),
- A table with the angle(s) measurement(s) and value(s) in degree (if any),
- At the bottom, the "Gleamer" logo and the "BoneMetrics" mention

5. Intended use/ Indications for Use

BoneMetrics US is a fully automated radiological image processing software device intended to aid users in the measurement of Cobb angles on frontal spine radiographs of individuals of at least 4 years old for patients with suspected or present spinal deformities, such as scoliosis. It should not be used instead of full patient evaluation or solely relied upon to make or confirm a diagnosis. The software device is to be used by healthcare professionals trained in radiology.

6. Substantial equivalence

Features and Characteristics	Subject Device Gleamer- BoneMetrics US	Predicate Device Ib Lab GmbH - Ib Lab LAMA (K223646)	Discussion of Differences and Comments
Regulation Information			
Classification regulation	21 CFR 892.2050- Medical image management and processing system	Same	N/A
Product Code	QIH	Same	N/A
Regulation Description	A medical image management and processing system is a device that provides one or more capabilities relating to the review and digital processing of medical images for the purposes of interpretation by a trained practitioner of disease detection, diagnosis, or patient management. The software components may provide advanced or complex image processing functions for image manipulation, enhancement, or quantification that are intended for use in the interpretation and analysis of medical images. Advanced image manipulation functions may include image segmentation, multimodality image registration, or 3D visualization. Complex quantitative functions may include semi-automated measurements or time-series measurements.	Same	N/A
Indications for use			

Features and Characteristics	Subject Device Gleamer- BoneMetrics US	Predicate Device Ib Lab GmbH - Ib Lab LAMA (K223646)	Discussion of Differences and Comments
Indications for use	BoneMetrics US is a fully automated radiological image processing software device intended to aid users in the measurement of Cobb angles on frontal spine radiographs of individuals of at least 4 years old for patients with suspected or present spinal deformities, such as scoliosis. It should not be used instead of full patient evaluation or solely relied upon to make or confirm a diagnosis. The software device is to be used by healthcare professionals trained in radiology.	IB Lab LAMA is a fully-automated radiological image processing software device intended to aid users in the measurement of limb-length discrepancy and quantitative knee alignment parameters on uni- and bilateral AP full leg radiographs of individuals at least 22 years of age. It should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis. The software device is intended to be used by healthcare professionals trained in radiology. IB Lab LAMA is not indicated for use on radiographs on which Ankle Arthroplasties and/or Unicompartmental Knee Arthroplasties are present.	The subject device performs measurements of Cobb angles on frontal spine images for patients of at least 4 years old. The predicate device performs measurements of lengths and angles on full leg images on patients of at least 22 years of age. This difference in anatomical measurements, anatomical locations, and patient population does not raise new types of questions for safety or effectiveness and therefore does not induce changes in the intended use. For both devices, the key question is whether the software is able to generate accurate and reproducible anatomical measurements within the target population. This is confirmed through additional controls that are in place to mitigate any risk for this difference: • dedicated training of the algorithm for the indications and the patient population • performance testing for all indications and populations

Features and Characteristics	Subject Device Gleamer- BoneMetrics US	Predicate Device Ib Lab GmbH - Ib Lab LAMA (K223646)	Discussion of Differences and Comments
Human Intervention for interpretation	Required	Same	N/A
Image requirements	DICOM compliant plain radiographs collected in other devices in the CR, DX formats.	Same	N/A
Anatomical area	Frontal Spine	Full leg	The anatomical area supported by the subject device (frontal spine) is different from the predicate device (full leg). This difference does not raise new questions regarding safety or effectiveness with respect to the technological characteristics. The techniques used for capturing full leg images and frontal spine images are both standard procedures. However, additional controls are in place to mitigate any risk for this difference: • dedicated training of the algorithm for the indications and the patient population • performance testing for all indications and populations
Technological Information			

Features and Characteristics	Subject Device Gleamer- BoneMetrics US	Predicate Device Ib Lab GmbH - Ib Lab LAMA (K223646)	Discussion of Differences and Comments
Workflow/ Principle of Operaion	1. User or PACS send image to the device 2. Device performs analysis 3. Image is sent back to PACS 4. User reviews the results	1. User or PACS send image to the device 2. Device performs analysis 3. Image is sent back to PACS 4. User reviews and accepts/rejects the results	N/A
Processing Architecture	1. Pre-process the input image 2. Classification of the image 3. Detect landmarks 4. Compute angles 5. Generate results	1. Pre-process the input image 2. Classify uni or bilateral image 3. Compute regions of interest for each side. 4. Detect landmarks and segmentations 5. Compute lines and distances 6. Compute angles 7. Generate reports	The Processing architecture is different between the subject and the predicate device: • The subject device does not perform a classification of uni or bilateral images. BMUS only process unilateral frontal spine images • The subject device does not compute regions of interest nor detected segmentations • The subject device only computes and does not compute distances or lines These differences are linked with the difference of indications for use mentionned above and the same additional controls are in place to mitigate these differences: • dedicated training of the algorithm for the indications and the patient population • performance testing for all indications and populations

Features and Characteristics	Subject Device Gleamer- BoneMetrics US	Predicate Device Ib Lab GmbH - Ib Lab LAMA (K223646)	Discussion of Differences and Comments
Technology	Convolutional neural networks for: • classification • landmarking Classical methods for computing: • angles	Convolutional neural networks for: • classification • landmarking • segmentation Classical methods for computing: • auxiliary points • lengths • angles	The technology behind the subject and the reference device is different: • The subject device does not provide segmentation or auxiliary points and lengths computing technology These differences are linked with the difference of indications for use mentionned above and the same additional controls are in place to mitigate these differences: • dedicated training of the algorithm for the indications and the patient population • performance testing for all indications and populations
Output	Human and machine readable results in the DICOM format.	Human and machine readable reports in the DICOM format.	N/A
Physical Characteristics	Software application.	Software application operated on OTS software.	N/A
Safety	Displayed warnings Intended Users: qualified and trained healthcare professionals Automated input checks: DICOM Tags check	Same	N/A

7. Performance data

Note: no animal testing or clinical testing is included in the current 510(k) submission.

7.1. Bench Testing - Nonclinical Tests

Product verification and validation testing were conducted and documented as per the requirements of the FDA guidance "Content of Premarket Submissions for Device Software Functions" for a Basic Documentation Level. Nonclinical tests include unit, integration and system levels testing for the final software version. BoneMetrics US performed as intended and all results observed were as expected. All software requirements and risk analysis have been successfully verified and traced.

7.2. Bench Testing - Clinical Performance Tests

A Clinical Standalone Performance Study was conducted on a dataset of 345 frontal spine radiographs of children and adults obtained from US data providers to validate the performance of BoneMetrics US.

The ground truth was determined by the expertise of two US board-certified musculoskeletal radiologists and one US board-certified orthopedic surgeon. These experts were kept unaware of the outputs from BoneMetrics US, findings from clinical reports, and readings from other truthers. The ground truth was defined as the mean of the Cobb angles values measured by the 3 ground truthers to establish a consensus-based ground truth. Any cases with discrepancies exceeding the predetermined threshold were subjected to an adjudication process, where the three experts mutually agreed on a value for the ground truth.

The clinical standalone performance study compared the performance of BoneMetrics US in the measurements of Cobb angles against a ground truth by computing the Mean Absolute Error (MAE) and an acceptance criteria.

Endpoint	Metric	Mean (95% CI)	Lower Bound	Upper Bound	Acceptance criteria
Cobb angle with the largest curvature n = 212	Mean Absolute Error (°)	2.56	2.0	3.28	Upper bound of the MAE 95% CI < 6.34°
Minor Cobb angle n = 189	Mean Absolute Error (°)	2.78	2.29	3.33	Upper bound of the MAE 95% CI < 6.34°

A subgroup analysis was performed for the performance accuracy of BoneMetrics US in adults, and children and pediatrics population.

Population	Endpoint	Metric	Mean (95% CI)	Lower Bound	Upper Bound	Acceptance criteria
Adults	Cobb angle with the largest curvature (n=100)	Mean Absolute Error (°)	3.31	2.21	4.87	Upper bound of the MAE 95% CI < 6.34°
	Minor Cobb angle (n=90)	Mean Absolute Error (°)	2.91	2.29	3.68	Upper bound of the MAE 95% CI < 6.34°
Children	Cobb angle with the largest curvature (n=32)	Mean Absolute Error (°)	1.34	0.88	1.86	Upper bound of the MAE 95% CI < 6.34°
	Minor Cobb angle (n=18)	Mean Absolute Error (°)	1.95	1.01	3.21	Upper bound of the MAE 95% CI < 6.34°
Adolescent	Cobb angle with the largest curvature (n=80)	Mean Absolute Error (°)	2.11	1.71	2.56	Upper bound of the MAE 95% CI < 6.34°
	Minor Cobb angle (n=81)	Mean Absolute Error (°)	2.83	1.96	3.85	Upper bound of the MAE 95% CI < 6.34°

The standalone results indicates that BoneMetrics US was able to meet the pre-defined performance acceptance criteria for Cobb angle measurements, thereby demonstrating its ability to provide clinically relevant measurements. The performance achieved by the device confirms that BoneMetrics US is an effective imaging device capable of providing reliable measurements of Cobb angles on frontal spine radiographs. Consequently, BoneMetrics US perform as intended and is considered substantially equivalent to the predicate device.

7.3. Conclusion

BoneMetrics US is as safe and effective as the predicate device. BoneMetrics US and the predicate device are both fully-automated radiological image processing software device intended to aid users perform measurements of interests on radiographs.

The overall design of the software and the basic functionality that it provides to the end user are the same. The minor differences between the subject and the 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 labelled. Verification and validation testing, including the clinical standalone software performance tests, supports the safety and demonstrates that BoneMetrics US performs as intended. Therefore BoneMetrics US is substantially equivalent.