January 17, 2025

Medimaps Group SA
% Giorgio Zoia
Quality and Regulatory VP, Medimaps SA Group
Chemin du Champ-des-Filles 36
Plan-les-Ouates, 1228
SWITZERLAND

Re: K243218
Trade/Device Name: TBS iNsight (V4)
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone Densitometer
Regulatory Class: Class II
Product Code: KGI
Dated: December 20, 2024
Received: December 20, 2024

Dear Giorgio Zoia:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems 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.

510(k) Number *(if known)*
K243218

Device Name
TBS iNsight (v4)

Indications for Use *(Describe)*
TBS iNsight is a software provided for use as a complement to both DXA analysis and clinical examination. It computes the antero-posterior spine DXA examination file and calculates a score (Trabecular Bone Score - TBS) that is compared to those of the age matched controls. The TBS is derived from the texture of the DXA image and has been shown to be related to bone microarchitecture.

TBS iNsight provides as an option an assessment of 10-year fracture risk. It provides an estimate of 10-year probability of hip fracture and 10-year probability of a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture). This estimate is based on the WHO's FRAX® Fracture Risk Assessment Tool, after adjustment for the TBS. The tool has been validated for Caucasian and Asian men and post-menopausal women between 40 and 90 years old.

TBS provides information independent of BMD value; it is used as a complement to the data obtained from the DXA analysis and the clinical examination (questioning by the clinician about patient history, bioassay of bone resorption markers…).

The results can be used by a physician in conjunction with other clinical risk factors as an aid in the diagnosis of osteoporosis and other medical conditions leading to altered trabecular bone microarchitecture, and ultimately in the assessment of fracture risk.

The TBS score can assist the health care professional in monitoring the effect of treatments on patients across time. Overall fracture risk will depend on many additional factors that should be considered before making diagnostic or therapeutic recommendations. The software does not diagnose disease or recommend treatment regimens. Only the health care professional can make these judgments.

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.

510(K) SUMMARY

Date: January 16, 2025

510(k) Number: K243218

1) Applicant Information

510(k) Owner: Medimaps Group SA

Chemin du Champ-des-Filles 36 Plan-les-Ouates

1228 Switzerland

Contact Person: Giorgio Zoia, PhD

Quality and Regulatory VP

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2) Device Identification

Trade Name: TBS iNsight (V4)

Common Name: Bone densitometer

Regulation Number : 892.1170

Regulation Name: Bone densitometer

Regulatory Class: II

Product Code: KGI

3) Predicate Device

Trade Name: TBS iNsight

510 (k) Number: K152299

Common Name: Bone densitometer

Regulation Number : 892.1170

Regulation Name: Bone densitometer

Regulatory Class: II

Product Code: KGI

Device Description Summary

TBS iNsight is a software application provided for use as a complement to bone mineral density (BMD) acquired from dual energy X-ray absorptiometry (DXA) and other clinical risk factors for osteoporosis and fragility fracture. It calculates a score (Trabecular Bone Score - TBS) derived from the texture of the DXA image of the anterior-posterior (AP) lumbar spine and has been shown to be related to bone microarchitecture. The method analyzes X-ray based images acquired by DXA imaging systems and produces the TBS based on the computation of an Adapted Experimental Variogram (modified fractal-like approach). This variogram is used to measure the degree of spatial variation between pairs of data points in a spatial dimension of a region of a digital image.

The absolute TBS values for the same equivalent tissue thickness vary slightly between GE and Hologic systems. Additionally, within each system, variability in TBS values can be observed across different scan modes. To address these differences, corrections are applied that are both device-specific and mode-specific. For instance, TBS is corrected differently for GE and Hologic systems to account for inherent differences in tissue thickness assessment. Furthermore, corrections are also tailored separately for each scan mode within the same system, ensuring that TBS measurements remain consistent and reliable regardless of the scan mode used. These device-specific and mode-specific corrections are necessitated by differences in the dynamic range of tissue thickness measurements between GE and Hologic devices. The variations arise due to differences in the methodologies used to assess tissue thickness. To harmonize these discrepancies and ensure measurement accuracy, correction fits derived from ex-vivo data are applied individually to each device and scan mode. This approach ensures the accuracy and consistency of TBS measurements across all configurations.

The device is intended to be used for bone health assessment in medical facilities employing one or more DXA system(s) to which the subject device is connected. These facilities are usually hospitals, clinics, healthcare centers, radiology practices and medical imaging centers. The software is designed to be used by qualified clinical professionals (including physicians, radiologists and DXA technicians) and the physicians are solely responsible for making all final patient management decisions.

Intended Use

TBS iNsight is indicated as an adjunct to BMD and other clinical factors, for the assessment of bone health and the management of primary and secondary osteoporosis. Primary osteoporosis can occur in both sexes with aging, and in females due to the menopause and associated estrogen deficiency. Secondary osteoporosis occurs as a result of an underlying disease or condition, which alters bone metabolism leading to a net loss of bone and degradation of bone quality, for example, diabetes, hyperparathyroidism, chronic kidney disease and rheumatological conditions.

Indication for Use

TBS iNsight is a software provided for use as a complement to both DXA analysis and clinical examination. It computes the antero-posterior spine DXA examination file and calculates a score (Trabecular Bone Score - TBS) that is compared to those of the age matched controls. The TBS is derived from the texture of the DXA image and has been shown to be related to bone microarchitecture.

TBS iNsight provides as an option an assessment of 10-year fracture risk. It provides an estimate of 10-year probability of hip fracture and 10-year probability of a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture). This estimate is based on the WHO's FRAX® Fracture Risk

Assessment Tool, after adjustment for the TBS. The tool has been validated for Caucasian and Asian men and post-menopausal women between 40 and 90 years old.

TBS provides information independent of BMD value; it is used as a complement to the data obtained from the DXA analysis and the clinical examination (questioning by the clinician about patient history, bioassay of bone resorption markers…).

The results can be used by a physician in conjunction with other clinical risk factors as an aid in the diagnosis of osteoporosis and other medical conditions leading to altered trabecular bone microarchitecture, and ultimately in the assessment of fracture risk.

The TBS score can assist the health care professional in monitoring the effect of treatments on patients across time.

Overall fracture risk will depend on many additional factors that should be considered before making diagnostic or therapeutic recommendations. The software does not diagnose disease or recommend treatment regimens. Only the health care professional can make these judgments.

Technological Comparison

The subject device, TBS iNsight V4, has been designed to maintain identical core functionalities as its predicate, specifically in the computation of Trabecular Bone Score (TBS) from DXA (Dual-energy X-ray Absorptiometry) image texture and the provision of complementary DXA analysis. TBS iNsight V4 and the predicate compute TBS from DXA image textures and provide complementary DXA analysis, ensuring continuity in the primary operational utility of the technology.

Differences:

- Algorithm for Tissue Thickness: Unlike the predicate device which uses BMI to estimate tissue thickness in its TBS computation algorithm, the subject device directly measures tissue thickness (TT) using the DXA system. This direct measurement potentially increases the accuracy of TBS calculations.

- System Architecture: The system architecture of the subject device represents an evolution from the standalone software model used in the predicate. The subject device includes a two-component system comprising a TBS Agent (client) installed on each DXA device and a centralized server that manages results and facilitates DICOM communication with PACS. This advancement supports enhanced scalability and integration within clinical settings.

- Data Security: TBS iNsight V4 introduces robust encryption protocols by incorporating encryption or role-based access control, aligning the new device with current best practices in data security.

Substantial Equivalence

Table 1. Substantial equivalence of TBS iNsight v4 to predicate device

Elements of Comparison	Subject device	Predicate Device	Comparison to predicate device
Device Name	TBS iNsight	TBS iNsight	Unchanged
Software Version	4	3	Updated
Manufacturer	Medimaps	Medimaps	Unchanged
510(k) #	K243218	K152299	N/A
Class	Class II	Class II	Unchanged

Elements of Comparison	Subject device	Predicate Device	Comparison to predicate device
Classification Rule / Name	21 CFR 892.1170 Bone Densitometer	21 CFR 892.1170 Bone Densitometer	Unchanged
Product Code	KGI	KGI	Unchanged
Level of Concern	Basic Documentation	Moderate	Unchanged
Intended Use	TBS is indicated as an aid, in conjunction with other clinical factors, for the diagnosis of primary and secondary osteoporosis. Primary osteoporosis can occur in both sexes with ageing, and in women due to the menopause and associated estrogen deficiency. Secondary osteoporosis occurs as a result of an underlying disease or condition, which alters bone metabolism leading to a net loss of bone and degradation of bone quality, for example, diabetes, hyperparathyroidism, chronic kidney disease and rheumatological conditions.	TBS is indicated as an aid, in conjunction with other clinical factors, for the diagnosis of primary and secondary osteoporosis. Primary osteoporosis can occur in both sexes with ageing, and in women due to the menopause and associated estrogen deficiency. Secondary osteoporosis occurs as a result of an underlying disease or condition, which alters bone metabolism leading to a net loss of bone and degradation of bone quality, for example, diabetes, hyperparathyroidism, chronic kidney disease and rheumatological conditions.	Unchanged
Indications for Use	TBS iNsight is a software provided for use as a complement to both DXA analysis and clinical examination. It computes the antero-posterior spine DXA examination file and calculates a score (Trabecular Bone Score - TBS) that is compared to those of the age matched controls. The TBS is derived from the texture of the DXA image and has been shown to be related to bone microarchitecture. TBS iNsight provides as an option an assessment of 10-year fracture risk. It provides an estimate of 10-year probability of hip fracture and 10-year probability of a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture). This estimate is based on the WHO's FRAX® Fracture Risk Assessment Tool, after adjustment for the TBS. The tool has been validated for Caucasian and Asian men and post-menopausal women between 40 and 90 years old. TBS provides information independent of BMD value; it is used as a complement to the data obtained from the DXA analysis and the clinical examination (questioning by the clinician about patient history, bioassay of bone resorption markers…). The results can be used by a physician in conjunction with other clinical risk factors as an aid in the diagnosis of osteoporosis and other medical conditions leading to altered trabecular bone microarchitecture, and ultimately in the assessment of fracture risk. The TBS score can assist the health care professional in monitoring the effect of treatments on patients across time. Overall fracture risk will depend on many additional factors that should be considered before making diagnostic or therapeutic recommendations. The software does not diagnose disease or recommend treatment regimens. Only the health care professional can make these judgments.	TBS iNsight is a software provided for use as a complement to both DXA analysis and clinical examination. It computes the antero-posterior spine DXA examination file and calculates a score (Trabecular Bone Score - TBS) that is compared to those of the age matched controls. The TBS is derived from the texture of the DXA image and has been shown to be related to bone microarchitecture. TBS iNsight provides as an option an assessment of 10-year fracture risk. It provides an estimate of 10-year probability of hip fracture and 10-year probability of a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture). This estimate is based on the WHO's FRAX® Fracture Risk Assessment Tool, after adjustment for the TBS. The tool has been validated for Caucasian and Asian men and post-menopausal women between 40 and 90 years old. TBS provides information independent of BMD value; it is used as a complement to the data obtained from the DXA analysis and the clinical examination (questioning by the clinician about patient history, bioassay of bone resorption markers…). The results can be used by a physician in conjunction with other clinical risk factors as an aid in the diagnosis of osteoporosis and other medical conditions leading to altered trabecular bone microarchitecture, and ultimately in the assessment of fracture risk. The TBS score can assist the health care professional in monitoring the effect of treatments on patients across time. Overall fracture risk will depend on many additional factors that should be considered before making diagnostic or therapeutic recommendations. The software does not diagnose disease or recommend treatment regimens. Only the health care professional can make these judgements.	Unchanged
Technological Characteristics			
Mode of operation	Dual Energy X-ray Absorptiometry	Dual Energy X-ray Absorptiometry	Unchanged
Input data	Raw DXA images and patient data	Raw DXA images and patient data	Unchanged
Measurements provided	- Lumbar Spine TBS	- Lumbar Spine TBS	Unchanged

Elements of Comparison	Subject device	Predicate Device	Comparison to predicate device
	- TBS T-Score and Z-score - TBS Category of fracture risk: normal, medium, or low - FRAX® Adjusted for TBS Estimate of 10-Year Fracture Risk based on clinical risk factors, BMD and TBS; indication of % probability of a hip fracture in the next 10 years and % probability of a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture) in the next 10 years.	- TBS T-Score and Z-score - TBS Category of fracture risk: normal, medium, or low - FRAX® Adjusted for TBS Estimate of 10-Year Fracture Risk based on clinical risk factors, BMD and TBS; indication of % probability of a hip fracture in the next 10 years and % probability of a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture) in the next 10 years.	
Target population	The intended patient population for TBS iNsight comprises both men and women, with its purpose for the assessment of bone health and fracture risk. Currently, TBS has not been validated for individuals younger than 20 years of age. The intended patient population for FRAX-adjusted by TBS are Caucasian and Asian men and women between 40 and 90 years old, for 10-year fracture risk assessment.	The intended patient population for TBS iNsight comprises both men and women, with its purpose for the assessment of bone health and fracture risk. Currently, TBS has not been validated for individuals younger than 20 years of age. The intended patient population for FRAX-adjusted by TBS are Caucasian and Asian men and women between 40 and 90 years old, for 10-year fracture risk assessment.	Unchanged
Users	DXA technologists, Physicians, Radiologists	DXA technologists, Physicians, Radiologists	Unchanged
DXA manufacturer supported	GE HC, Hologic	GE HC, Hologic	Unchanged
Segmentation	Automatic ROI segmentation, possibly corrected manually	Automatic ROI segmentation, possibly corrected manually	Unchanged
Functionality	- Computes TBS from DXA image texture. Outputs complement DXA analysis.	- Computes TBS from DXA image texture. Outputs complement DXA analysis.	Unchanged
-Algorithm for Tissue Thickness	Directly uses tissue thickness (TT) measured by the DXA, in the TBS computation algorithm.	Uses BMI to estimate tissue thickness (TT) in the TBS computation algorithm.	Updated
-System Architecture	-Two components: TBS Agent (client) installed on each DXA and a centralized server that manages results and DICOM communication with PACS.	Standalone software installed on the DXA system, capable of communicating with PACS.	Updated
Data security	Implements encryption for data at rest and in transit, as well as role-based access control to enhance cybersecurity.	No encryption or role-based access control.	Updated

Performance Testing Summary & Conclusions

Standalone Performance Testing Summary

The primary advancement in TBS version 4.0 is the replacement of BMI-based adjustments with direct measurement of tissue thickness from DXA scan images. A series of validation studies confirm the performance, accuracy, and reproducibility of TBS version 4.0 compared to the predicate device.

Software Verification and Validation demonstrate specified requirements are met and the software functions as intended. Cybersecurity controls and processes have been implemented to ensure the software and related systems are cybersecure. Cybersecurity documentation and testing demonstrates the software, and related systems are in alignment with the recommendations in the “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions” guidance as well as the requirements of Section 524B of the FD&C Act.

Clinical Association

Two pivotal studies validated the ability of TBS version 4.0 to accurately reflect bone microarchitecture. The first study evaluated the correlation between TBS values and bone microarchitecture parameters using 30 human cadaver lumbar vertebrae. Micro-computed tomography (microCT) measurements were compared to TBS values, revealing strong and statistically significant correlations with parameters such as trabecular number and separation. The results demonstrated that TBS version 4.0 maintained or exceeded the correlations established with the predicate, ensuring its validity in reflecting bone microarchitecture.

The second study examined the agreement between TBS version 4.0 and the predicate software using 15 human cadaver vertebrae. Measurements were performed on multiple DXA systems, and the analysis showed excellent agreement, with correlation coefficients exceeding 0.99. Bland-Altman statistics confirmed negligible differences between versions, supporting the consistency and reliability of TBS version 4.0 across different DXA platforms.

Analytical Reproducibility

The reproducibility of TBS measurements with version 4.0 was evaluated in both ex vivo and in vivo settings. In the ex vivo study, measurements from dried human lumbar vertebrae demonstrated that TBS version 4.0 provides precision and least significant change (LSC) values that are comparable to or slightly improved over those of the predicate. These results were consistent across various DXA systems.

In vivo testing involved 132 participants scanned on four different DXA systems. The analysis included repositioning between scans to assess precision and reproducibility under clinical conditions. Results showed that TBS version 4.0 met or exceeded precision standards established by the International Society for Clinical Densitometry (ISCD), with LSC values within acceptable thresholds. This level of precision helps to support the utility of TBS version 4.0 to assist physicians in monitoring bone health over time.

Performance and Utility

The performance and utility of TBS version 4.0 were evaluated across diverse scenarios, including fracture risk assessment, population-specific reference curves, and monitoring treatment responses. A key advancement of the software is the transition from BMI-based adjustments to direct measurements of tissue thickness. This was validated in-vivo, establishing a valid tissue thickness range of 7–30 cm, which aligns with the physiological parameters relevant to TBS calculations.

The generation of population-specific reference curves for age, sex, and ethnicity demonstrated the applicability of TBS version 4.0 across diverse demographic groups, including multi-ethnic populations in the United States. Comparisons with the predicate software confirmed statistical equivalence, reinforcing the reliability of the subject device in representing bone health across different populations.

For fracture risk assessment, data from over 17,000 individuals across 14 international cohorts were analyzed to compare the performance of TBS-adjusted FRAX and BMD T-scores using the updated software. TBS version 4.0 demonstrated similar TBS-adjusted FRAX and BMD T-scores for major osteoporotic and hip fractures than the predicate.

Additionally, data from a large cohort of postmenopausal women with osteoporosis, demonstrated the effectiveness of TBS version 4.0 for accurately outputting TBS-adjusted FRAX and BMD T-scores for major osteoporotic and hip fractures over time in order to assist physicians with treatment monitoring, with substantial equivalence to the predicate.

Conclusion

TBS version 4.0 demonstrates substantially equivalent performance in the assessment of bone quality and TBS-adjusted FRAX and BMD T-scores. Standalone validation studies confirm the performance, reliability, and utility of the updated software across diverse populations and DXA systems