



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

Medimaps Group SA  
% Mr. Christophe Lelong  
Chief Technical Officer  
18, Chemin des Aulx  
CH-1228 Plan les Ouates  
SWITZERLAND

April 29, 2016

Re: K152299  
Trade/Device Name: TBS iNsign  
Regulation Number: 21 CFR 892.1170  
Regulation Name: Bone Densitometer  
Regulatory Class: II  
Product Code: KGI  
Dated: March 22, 2016  
Received: March 25, 2016

Dear Mr. Lelong:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned above the typed name and title.

For

Robert Ochs, Ph.D.  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K152299

Device Name  
TBS iNstight

### Indications for Use (Describe)

TBS iNstight 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 iNstight 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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

This summary of the 510(k) Premarket Notification for the TBS iNsight software is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**The assigned 510(k) number is : K152299**

**Owner:** Medimaps group  
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1294 Plan les Ouates  
Switzerland

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**Fax:** + (41) 22 794 66 65

**Contact Person:** Christophe Lelong  
Chief Technology Officer  
e-mail: clelong@medimapsgroup.com

**Date Prepared:** April 25, 2016

**Device Names:**  
**Trade/Proprietary Name:** TBS iNsight  
**Common or Usual Name:** TBS iNsight® software, and its calibration phantom, for analysis of bone microarchitecture and osteoporosis management.

**Device Class** Class II  
**Classification Name:** 21 CFR 892.1170 - Bone Densitometer  
**Product Code:** KGI

## **DEVICE DESCRIPTION**

TBS iNsight is a software provided for use as a complement to both DXA analysis and clinical examination. It computes the AP spine DXA examination file and calculates the 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.

It provides as an option an assessment of 10-year fracture risk, based on the WHO's FRAX® Tool, after adjustment for the TBS.

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.

## **INTENDED USE / 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.

## PREDICATE DEVICES

The TBS iNsight software is considered substantially equivalent to FDA cleared predicate devices with regards to both indications for use and technological characteristics.

In that both TBS iNsight and its predicate devices provide an assessment of the risk for fracture of patients based on DXA scans.

This predicate devices are Med-Imaps TBS iNsight, cleared under K121716, and GE Lunar FRAX™ 10-year Fracture Risk software option, cleared under K082317.

## SUBSTANTIAL EQUIVALENCE

The following table provides a more detailed substantial equivalence discussion :

	<b>Subject Device</b>	<b>Predicate Device 1</b>	<b>Predicate Device 2</b>
<b>Product Name</b>	<b>TBS iNsight</b>	<b>TBS iNsight</b>	<b>GE Lunar FRAX™ 10-year Fracture Risk software option</b>
Classification	Class II	Identical	Identical
Product Code	KGI	Identical	Identical
Classification Name	Bone Densitometer	Identical	Identical
Classification Rule	21 CFR 892.1170	Identical	Identical
510(k)	K152299	K121716	K082317
<b>Intended use</b>	<p>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.</p> <p>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.</p> <p>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...).</p> <p>The results can be used by a physician in conjunction with other clinical risk factors as an aid in the diagnosis of</p>	<p>The Med-Imaps TBS iNsight is a software provided for use as a complement to a DXA analysis. 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 and fracture risk.</p> <p>This data 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...).</p>	<p>The FRAX™ 10-Year Fracture Risk software option is an accessory to currently marketed GE Lunar bone densitometer devices, which are intended to estimate the bone mineral density and body composition (lean and fat tissue mass) of patients when medically indicated by their physicians.</p> <p>This software option is intended to provide an assessment of 10-year fracture risk. The option 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 patient's age, sex, country, ethnicity, height, weight, femur neck BMD T-score, and the presence or absence of several risk factors and is computed using the FRAX™ Fracture Risk Assessment Tool endorsed by the World Health Organization (WHO). The tool has been validated for men and post-menopausal women between 40 and 90 years old. The output is provided in a separate screen display and report that can be viewed or printed or exported to an optional physician report generator tool.</p> <p>The results can be used by a physician in conjunction with other clinical risk factors as an aid in the diagnosis of</p>

	Subject Device	Predicate Device 1	Predicate Device 2
Product Name	TBS iNsight	TBS iNsight	GE Lunar FRAX™ 10-year Fracture Risk software option
	<p>osteoporosis and other medical conditions leading to altered trabecular bone microarchitecture, and ultimately in the assessment of fracture risk.</p> <p>The TBS score can assist the health care professional in monitoring the effect of treatments on patients across time.</p> <p>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.</p>	<p>The TBS score can assist the health care professional in assessment of fracture risk and in monitoring the effect of treatments on patients across time.</p> <p>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.</p>	<p>osteoporosis and medical conditions leading to reduced bone density, and ultimately in the assessment of fracture risk.</p>
Software Level of concern	Moderate	Identical	Identical
Technique	Dual Energy X-ray Absorptiometry (DXA)	Identical	Identical
Input Data	Raw DXA images and patients data	Identical	Identical
Measurements provided	<ul style="list-style-type: none"> <li>•Lumbar Spine TBS</li> <li>•TBS T-score and Z-score</li> <li>•TBS Category of fracture risk: high, medium, or low</li> <li>•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 or % probability of a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture) in the next 10 years.</li> </ul>	<ul style="list-style-type: none"> <li>•Lumbar Spine TBS</li> <li>•Indication of fracture risk based on the patient's TBS</li> </ul>	<ul style="list-style-type: none"> <li>•Lumbar Spine BMD</li> <li>•Femur BMD</li> <li>•BMD T-score and Z-score</li> <li>•WHO Category of bone loss: normal, osteopenia (low bone mass), or osteoporotic</li> <li>•WHO FRAX™ Estimate of 10-Year Fracture Risk based on BMD and clinical risk factors: Indication of % probability of a hip fracture in the next 10 years or % probability of a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture) in the next 10 years.</li> </ul>

Based on the comparison given above and the discussion of the intended use, technological characteristics, input data and measurements provided by the subject and predicate devices, the subject device is substantially equivalent to the cited predicate devices.

## **CONFORMITY TO RECOGNISED STANDARDS**

TBS iNsight has been developed in accordance with the following product standards & FDA Guidance :

- I. IEC 62304:2006, Medical Device Software: Software Life Cycle Processes
- II. ISO 14971:2007, Medical Devices: Application of Risk Management to Medical Devices
- III. General Principles of Software Validation; Final Guidance for Industry and FDA Staff (2002)
- IV. Guidance for Off-the-Shelf Software Use in Medical Devices (1999)
- V. Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the Shelf (OTS) Software (2005)

## **PERFORMANCE BENCH TESTING**

No new bench testing since K121716.

## **CLINICAL TESTING**

The performance of TBS iNsight was evaluated via clinical studies covering the following :

- Clinical Aspects – FRAX adjusted for TBS  
*TBS is an independent clinical risk factor for fracture and can be used in association with WHO's FRAX® to adjust and improve the FRAX® probability of hip fracture and of major osteoporotic fracture in postmenopausal women and in men. This was demonstrated using 3 published studies and a report provided by the Frax group to Medimaps.*
- Clinical Aspects – TBS iNstats  
*TBS iNsight provides a breakdown of the patients DXA exams based on their BMD and TBS values. The fracture risk in each cell has been evaluated based on a cohort of 29,000 Canadian women. Two studies have been used to demonstrate that the TBS categories of fracture risk computed from the Canadian study are applicable to the US population and another study to demonstrate that the TBS values of the population included in the Canadian study are similar to the normal TBS values of the US population.*
- Normative data  
*A US clinical study including Non-Hispanic white US women and men, Non-Hispanic black US women and men and Mexican American women and men, aged 20 to 85 years has been conducted. The data provided from the Nhanes IV database, which is the reference database for the US. TBS values obtained for all lumbar vertebral combinations (L1, L2, L3, L4) decreased significantly with age. These decreases seen in lumbar spine TBS reflect the age-related microarchitecture changes at spine.*

Based on this clinical studies, no new questions arise regarding the safety and effectiveness of this device, which can be considered substantially equivalent to the predicate devices.

## **CONCLUSION**

Medimaps group has demonstrated through the testings that the safety and effectiveness of TBS iNsight is not compromised and that they met all acceptance criteria, demonstrating that it can be considered substantially equivalent to the predicate devices.