510k Summary

This summary of the 510(k) Premarket Notification for the medimaps group 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 : K121716

OCT 5 2012

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Contact Person:	Christophe Lelong Chief Operations Officer e-mail: clelong@med-imaps.com

Date Prepared:	June, 4, 2012
Device Names:	
Trade/Proprietary Name:	TBS iNsight
Common or Usual Name:	Bone microarchitecture assessment from medical imaging
Device Class	Class II
Classification Name:	21 CFR 892.1170 - Bone Densitometer
Product Code:	KGI

DEVICE DESCRIPTION

TBS iNsight is a software package that provides an estimate of the trabecular bone quality based on analysis of data derived from DEXA examination. The program utilizes a quantitative bone structural algorithm that analyzes the texture of AP spine projection scans from which the Trabecular Bone Score (TBS) is mathematically derived.

The results (TBS) can be used for comparison to a reference database of age-matched controls.

INTENDED USE / INDICATIONS FOR USE

The Med-Imaps TBS iNsight is a software provided for use as a complement to a DEXA analysis. It computes the antero-posterior spine DEXA 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 DEXA image and has been shown to be related to bone microarchitecture and fracture risk. This data provides information independent of BMD value; it is used as a complement to the data obtained from the DEXA analysis and the clinical examination (questioning by the clinician about patient history, bioassay of bone resorption markers...).
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.
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 DEVICE

The TBS iNsight software is considered substantially equivalent to FDA cleared predicate device with regards to both indications for use and technological characteristics.
In that both systems use previously acquired x-ray images to provide an estimate of the bone strength and a comparison to a normative data cohort for interpretation.

This predicate device is Imaging Therapeutics OsDx Hip BMD System, cleared under K082402.

SUBSTANTIAL EQUIVALENCE

The following table provides a more detailed substantial equivalence discussion :

	Predicate Device	**Subject Device**
Product Name	**OsDx Hip BMD System** (K082402)	**TBS iNsight**
Classification	Class II	Identical
Product Code	KGI	Identical
Classification Name	Bone Densitometer	Identical
Classification Rule	21 CFR 992.1170	Identical
Device Description	The OsDx Hip BMD System is a software package that provides an estimate of BMD based on analysis of data derived from scanned hip X-rays. The program utilizes a quantitative bone structural algorithm that measures a composite of weighted cortical and trabecular parameters in proximal femur projection radiographs from which total hip bone mineral density (BMD) is mathematically derived. Image analysis can take place remotely or at the point of care. The results, expressed as gm/cm², can be used for comparison to a reference data base of young normals (T-score) or age-matched controls (Z-Score).	TBS iNsight is a software package that provides an estimate of the trabecular bone quality based on analysis of data derived from DEXA examination data (dual-energy images, Regions of interest, patients' data). The program utilizes a quantitative bone structural algorithm that analyzes the texture of AP spine projection scans from which the Trabecular Bone Score (TBS) is mathematically derived. The results (TBS) can be used for comparison to a reference database of age-matched controls.
Data source	Importation of external data source	Identical
Imaging technology	X-Ray absorption	Identical
Data analysis method	Data image processing Algorithm Quantitative bone structural algorithm that measures a composite of weighted cortical and trabecular parameters in proximal femur projection radiographs from which BMD is mathematically derived	Identical Quantitative bone micro-structural algorithm that analyzes the porosity of the trabecular bone in DEXA projection images, using the experimental variogram approach from which the TBS is mathematically derived

	Predicate Device	Subject Device
Product Name	**OsDx Hip BMD System** (K082402)	**TBS iNsight**
Data Output	Estimate of Bone Mineral Density (BMD) on selected ROI Combines measurements of projected trabecular bone pattern, with cortical bone and geometric dimensions to estimate the total hip BMD	TBS calculated on selected ROI Analyses projected trabecular bone pattern to estimate the trabecular bone score (TBS)

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

Bench Test Performance was demonstrated via the following :

- Correlations between microarchitecture and TBS computed on simulated projections from µCT datasets

  This study was to demonstate the level of correlation between the microarchitecture parameters of the 3-dimensional (3D) bone volume using a µCT (GE-Locus) and the TBS values computed on the 2D projected image of the bone volume, using thirty human cadaveric vertebrae.
  Significant correlations were observed between TBS and 3D microarchitecture parameters, regardless of the projection resolution.

- Correlations between microarchitecture and TBS on DEXA scans

  This study was to demonstrate the correlations between the 3D microarchitecture parameters of human anteroposterior vertebrae and the TBS values computed on DEXA (Dual X-ray Absorptiometry) acquisitions, using thirty human cadaveric vertebrae.
  Significant correlations were detected between TBS and 3D parameters of bone microarchitecture.
  The study indicates that TBS adds value and power of differentiation between samples with similar BMDs but different bone microarchitectures. It strengthens our assumption that it is possible to estimate bone microarchitecture status from DEXA imaging using TBS.

- TBS reproducibility ex-vivo

  This study is to evaluate the ex-vivo reproducibility of TBS without repositioning.

The study shows that the TBS ex-vivo precision error is lower than 0.02, the reproducibility is lower than 1.5 %, and the least significant change is lower than 4.2 %.
These results show that TBS is reproducible and, considering measurement rules edited by the ISCD, can be used to monitor microarchitecture changes across time.

CLINICAL TESTING

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

- Clinical Aspects – diagnostic value
  TBS iNsight capability to discriminate a fractured patient from a control patient (non-fractured), independently and in conjunction with BMD, has been evaluated through five cross-sectional studies.
  In all studies TBS was significantly lower in women with fractures versus without.
- Clinical Aspects – prognostic value
  TBS iNsight capability to identify patients that will fracture from those who will not, independently and in conjunction with BMD, has been evaluated through three longitudinal studies.
  In all studies spine TBS and BMD predicted fractures equally well and independently.
- Clinical Aspects
  - Monitoring changes across time
    In the two in-vivo reproducibility studies that were conducted, the mean TBS reproducibility value (CV%) at L1-L4 achieved 1.8%, showing that TBS is reproducible as the BMD and considering rules edited by the ISCD.
  - Treatment follow-up
    Six in-vivo studies were conducted to compare the changes in lumbar spine BMD and TBS values in patients treated either with zoledronic acid (vs placebo), teriparatide (vs ibandronate) or bisphosphonates (vs placebo), Strontium Ranelate (vs Alendronate), Tamoxifen & Exemestane (vs placebo) and Denosumab (vs placebo). For all six studies, the results were consistent with published literature.
    These study demonstrate that TBS iNsight can be used by the physicians to monitor change across time, particularly for treated patients.
- Clinical Aspects – Age-related US reference data
  A US clinical study including Non-Hispanic white US women aged 30 to 90 years has been conducted. TBS values obtained for all lumbar vertebral combinations (L1, L2, L3, L4) decreased significantly with age. These decreases seen in lumbar spine TBS reflect age-related microarchitecture changes at spine.

CONCLUSION

medimaps group has demonstrated through the performance testing 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 device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

MEDIMAPS Group SA
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OCT 5 2012

Re: K121716
Trade/Device Name: Med- Imaps TBS iNsight
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone Densitometer
Regulatory Class: Class II
Product Code: KGI
Dated: August 24, 2012
Received: August 30, 2012

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

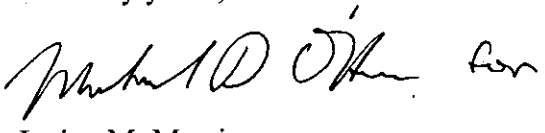
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

The Med-Imaps TBS iNsight is a software provided for use as a complement to a DEXA analysis. It computes the antero-posterior spine DEXA 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 DEXA image and has been shown to be related to bone microarchitecture and fracture risk. This data provides information independent of BMD value; it is used as a complement to the data obtained from the DEXA analysis and the clinical examination (questioning by the clinician about patient history, bioassay of bone resorption markers...).

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Prescription Use __X__ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121716