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510(k) Summary
[This 510(k) summary is furnished in accordance with 21 CFR 807.92]

21 CFR 807.92(a):

21 CFR 807.92(a)(1):

* Submitter's name and address:

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* Submitter's telephone number: 011 45 44 92 42 00

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* Date this 510(k) summary was prepared: March 11, 1996

21 CFR 807.92(a)(2):

* Trade/proprietary name of the device: DTX-200 Bone Densitometer

* Classification name: Bone densitometer

21 CFR 807.92(a)(3); Legally marketed device (predicate device) to which equivalence is claimed:

* Osteometer MediTech A/S model DTX-100 bone densitometer

* Hologic, Inc. model QDR-1000/W bone densitometer

21 CFR 807.92(a)(4); Description of the device that is the subject of this premarket notification:

The DTX-200 candidate device is a dual energy system, where the measured object, in this case the forearm, by the software, is divided into two compartments, bone and soft-tissue. Having two energies, and two compartments (unknowns) it is possible to establish and solve two formulae with two unknowns.

The X-Ray generator is driven at 55 kV , with a current of 300

μAmps. The beam is filtered with Tin (Sn), using the K-Edge of this material to enhance the separation of the low and the high energy. The average energy peaks are approximately 29 keV, and 46 keV respectively. A highly stable X-Ray output, together with a source collimation of 1 mm and a pixel resolution of 0.4mm X 0.4mm, yields images of very high quality.

The detector is a sandwich construction, using solid state photo-diodes consisting of two diodes with scintillation material. The two energies are separated by the sandwich construction. The X-ray beam meets the first scintillator, where predominantly the low energy is detected, and then it meets the second scintillator, where the rest of the energy is detected.

The typical time to estimate bone mineral content and bone mineral density is approximately 4 minutes. The effective patient dose is estimated to be 0.1 micro Sievert per scan.

21 CFR 807.92(a)(5); Intended use:

The intended use of the DTX-200 candidate device is the same as the labeled intended use of the predicate devices to which equivalence is claimed; i.e., "To estimate bone mineral content (BMC, grams) and bone mineral density (BMD, grams/cm^2).

21 CFR 807.92(a)(6); Technological characteristics:

The design, material, chemical composition, energy source and other technological characteristics of the subject device are considered to be the same as the technological characteristics of the predicate devices. A summary of the technological characteristics of the subject device in comparison to those of the predicate devices follows:

* **X-ray transmission source:**

  Both the DTX-200 subject and the DTX-100 predicate bone densitometer devices consist of a computer, keyboard, monitor, printer, and scanner system using an X-ray transmission source. The DTX-200 candidate device uses dual X-ray photon absorptiometry (DXA), the DTX-100 predicate device uses single X-ray photon absorptiometry (SXA), and the QDR-1000/W predicate device uses dual energy quantitative digital radiography to estimate bone mineral content (BMC) and bone mineral density (BMD).

* **Soft-tissue equivalent material:**

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In contrast to the DTX-100 predicate device (that uses water as soft tissue equivalent material) and the QDR-1000/W predicate device (that uses a calibration wheel), the DTX-200 candidate device does not require the use of water as an soft tissue equivalent material. The precision of the devices is comparable.

* **Calibration:**

  Both the DTX-200 candidate device and the DTX-100 predicate device use a line-by-line calibration system, ensuring good precision. The QDR-1000/W predicate device self calibrates using an automatic internal reference system.

* **Imaging technique, data acquisition, and quality control phantom:**

  These characteristics are the same on the DTX-200 candidate device as the DTX-100 predicate device.

* **Source collimation:**

  The source collimation for both the DTX-200 candidate device and the DTX-100 predicate device is the 1 mm diameter. The source collimation for the QDR-1000/W predicate device is pencil beam, 0.09 inch diameter.

* **Reference location:**

  The reference location for both the DTX-200 candidate device and the DTX-100 predicate device is the 8 mm Ulna-Radius gap. The reference location for the QDR-1000/W predicate device is the ulnar styloid.

* **Accuracy and precision error:**

  Accuracy and precision error of the DTX-200 candidate device is comparable to that of the DTX-100 predicate device and the QDR-1000/W predicate device.

21 CFR 807.92(b);

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510(k) summaries for those premarket submissions in which a determination of substantial equivalence is also based on performance data shall also contain the following:

21 CFR 807.92(b)(1); Brief discussion of the nonclinical tests submitted, referenced, or relied on in this premarket notification submission:

There were no nonclinical tests submitted, referenced, or relied on in this submission.

21 CFR 807.92(b)(2); Brief discussion of the clinical tests submitted, referenced, or relied on in this premarket notification submission:

The results of seven (7) clinical tests were submitted, referenced, or relied on in this premarket submission. Two clinical tests were sponsored by the device manufacturer and five of the clinical studies were from published literature:

1. Two clinical tests sponsored by the device manufacturer; (A) a functional correlation study between the DTX-200 candidate device and the DTX-100 predicate device and (B) a precision study of the DTX-200 candidate device.

A. Functional Correlation Study: Bone mineral content (BMC) and bone mineral density (BMD) were measured at the 8 mm distal site and the ultra distal site in the nondominant forearm of eighty one (81) individuals to determine the functional relationship and to evaluate the degree of correlation between the DTX-200 candidate device and the DTX-100 predicate device. Linear regression analysis was used to determine the degree of correlation.

B. Precision Study: Bone mineral content (BMC) and bone mineral density (BMD) were measured at the 8 mm distal site and the ultra distal site in the nondominant forearm of fifteen (15) individuals, five (5) times each, to estimate the precision error of the DTX-200 candidate device. The precision estimates were calculated as the coefficient of variation at a 95% confidence interval using log-transformed data.

2. Five of the clinical studies were from published literature:

A. "Bone Changes Occurring Spontaneously and Caused by Oestrogen in Early Postmenopausal Women: A Local or

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Generalized Phenomenon?" Published in the British Medical Journal, 26th. April 1986, by Anders Gotfredsen, Lisbeth Nilas, Bente Juel Riis, Karsten Thomsen, and Claus Christiansen.

Abstract of this clinical study:

> "Regional values of bone mineral content and bone mineral density were calculated from total body and dual photon absorptiometry scans of 52 early postmenopausal women treated with placebo. The six regions were head, arms, chest, spine, pelvis, and legs. In addition, bone mineral density of the lumbar spine was measured by dual photon absorptiometry and bone mineral content of the forearm using single photon absorptiometry, using separate special purpose scanners. All regions were unchanged after one year of treatment with oestrogen, excluding the lumbar spine, for which values rose. Values for all regions except the lumbar spine fell significantly in the placebo group. The rates of loss ranged from 2% to 8%, with no significant differences among the regions."

B. "Single X-Ray Absorptiometry of the Forearm: Precision, Correlation, and Reference Data". Published in Calcified Tissue International, in 1994, by T.L. Kelly, G. Crane, and D.T. Baran.

Abstract of this clinical study:

> "The performance of a single X-ray absorptiometry (SXA) device incorporating an X-ray tube as a photon source was evaluated with respect to precision in vivo and in vitro, scan time, image quality, and correlation with an existing dual energy X-ray absorptiometry (DXA) device. SXA precision in vivo, expressed as a coefficient of variation (CV), was 0.66% for bone mineral content (BMC) and 1.05% for bone mineral density (BMD). Precision in vitro, based on 78 measurements of a forearm phantom over 195 days, was 0.53%. Correlation with DXA at the 8 mm distal forearm site was high ($r = 0.97$ for BMC and $r = 0.96$ for BMD). A preliminary SXA reference data base composed of 151 healthy Caucasian American women was developed to facilitate the interpretation of patient measurements. SXA scan time was 4 minutes

and delivered a radiation exposure of 1.68 mrem. SXA image quality and spatial resolution were superior to SPA and comparable to DXA."

C. "Impact of Soft Tissue on In Vivo Accuracy of Bone Mineral Measurements in the Spine, Hip, and Forearm: A Human Cadaver Study". Published the Journal of Bone and Mineral Research, Volume 10, Number 6, 1995, by Ole L. Svendsen, Christian Hassager, Vera Skodt, and Claus Christiansen.

Abstract of this clinical study:

"The impact of soft tissue in vivo based on bone mineral density (BMD) measurements of the spine and hip by dual energy X-ray absorptiometry and of the forearm by single photon absorptiometry was assessed by use of 14 human cadavers. The in vivo accuracy errors (SEE%) were: forearm 3-5%, anteroposterior spine 5.3%, lateral spine 10-12%, and femoral greater trochanter, neck, total, intertrochanteric, and Ward's triangle 3%, 6.5%, 6.7%, 8%, and 11-13%, respectively. Except from the lateral spine and the greater trochanter, the slopes of the linear regressions of in vivo BMD against an in vitro BMD were not significantly different from 1($p > 0.05$). The calculated random accuracy error of BMD measurements due to fat inhomogeneity was estimated to 3-4% for the anteroposterior spine and 9-14% for the lateral spine (from abdominal computed tomography in 26 healthy women)."

D. "Dual-Energy X-Ray Absorptiometry: A Precise Method of Measuring Bone Mineral Density in the Lumbar Spine". Published in The Journal of Nuclear Medicine, July 1990, by Marc A. Hansen, Christian Hassager, Kirsten Overgaard, Ulla Marslew, Bente J. Riis, and Claus Christiansen

Abstract of this clinical study:

"We compared two methods of measuring spinal bone mineral content and density (BMC/BMD): conventional dual-photon absorptiometry (DPA) and a more recent method, dual energy X-ray absorptiometry (DEXA). The clinical usefulness of both methods was compared in the measurement of BMC in the forearm. DEXA had a long term in vivo precision of 1% which

was significantly better than that of DPA. Changes in the distribution of fatty tissue influenced the accuracy of the two spinal methods in different ways. Forearm BMC discriminated between the bone mass of early and late postmenopausal women to the same degree as DPA and DEXA. The variability in the response to the estrogen treatment and placebo with DEXA and forearm BMC than with DPA."

E. "Patient Dose in Dual X-Ray Absorptiometry". Published in Osteoporosis International, (1994) 4:11-15, by M.K. Lewis, G.M. Blake, and I. Fogelman.

Abstract of this clinical study:

"Dual X-ray absorptiometry (DXA) provides a convenient, non-invasive method of assessing skeletal bone mineral which is widely used for clinical studies. This report describes a study to estimate dose of radiation [ICRP-60 (1990)] to a female patient from scans performed on three DXA scanners: the Hologic QDR-1000, QDR-1000/W and QDR-2000. The scans modes studied were: total body; anteroposterior (AP) lumbar spine; lateral lumbar spine; proximal femur; distal forearm. An ion chamber and tissue-equivalent phantom were used to determine entrance surface dose and percentage depth-dose curves for each scan mode. Anatomical data from ICRP-23 (Reference Man) and a body section atlas were used to estimate the absorbed dose to each organ in the scan fields. Effective dose was estimated using the ICRP-60 tissue weighing factors and the fraction of each organ in the scan field.

21 CFR 807.92(b)(3; The conclusions drawn from the nonclinical and clinical tests that demonstrate that the subject device is as safe, as effective, and performs as well as or better than the predicate device:

Clinical studies sponsored by Osteometer MediTech A/S:

1A. Functional Correlation Study: The clinical study on eighty one (81) patients showed the DTX-200 candidate device and the DTX-100 predicate device are substantially equivalent in their ability estimate bone mineral content (BMC) and bone

mineral density (BMD).

1B. Precision Study: The results of the clinical study on fifteen (15) individuals shows that the DTX-200 candidate device estimates bone mass with precision errors in an order that makes it possible to detect clinically meaningful differences between repeated bone scans in the same individual.

Clinical studies published in the literature:

2A. "Bone Changes Occurring Spontaneously and Caused by Oestrogen in Early Postmenopausal Women: A Local or Generalized Phenomenon?" This study concluded, "Loss of bone in early menopause is a generalized phenomenon, affecting all parts of the skeleton. Furthermore, oestrogen prophylaxis for loss of bone is effective in all parts of the skeleton. Finally, it is suggested that the measurement of bone mineral content in the forearm should be used for clinical follow up of bone changes, as this method is superior to others in the ratio of change to precision."

2B. "Single X-Ray Absorptiometry of the Forearm: Precision, Correlation, and Reference Data": This study concluded, "SXA image quality and spatial resolution were superior to SPA and comparable to DXA."

2C. "Impact of Soft Tissue on In Vivo Accuracy of Bone Mineral Measurements in the Spine, Hip, and Forearm: A Human Cadaver Study": This study concluded, " Acceptable accuracy errors below 6-7% (of soft tissue in vivo) of BMD measurements were obtained in the anteroposterior spine, the forearm, and the neck, greater trochanter, and total proximal femur."

2D: "Dual-Energy X-Ray Absorptiometry: A Precise Method of Measuring Bone Mineral Density in the Lumbar Spine": This study concluded, "that DEXA provides a fast and precise measurement of spinal BMC/BMD. The accuracy remains to be evaluated for in vivo studies "

2E. "Patient Dose in Dual X-Ray Absorptiometry": This study concluded, "PDD (percentage depth dose) curves for the QDR-1000 and the QDR-1000/W part-body scans were found to be identical, with ESD (entrance skin dose) varying according to the speed of the scanning arm. The QDR-2000 pencil beam PDD curves were identical to those for the QDR-1000 and the QDR-1000/W with the ESD a factor of 1.6 higher due to the use of a lighter scanning table. The PDD curves for the QDR-2000 1-

min, 2-min and 3-min fan beam spine and hip scans were identical with ESD measurements varying in proportion with scanning speed. As would be expected from the ESD and PDD curve data the effective doses for scans performed on the QDR-1000 and QDR-1000/W were identical while those for the QDR-2000 pencil beam mode were higher by a factor of 1.6."

.... END OF 510(k) SUMMARY ....