

Appendix E

510(k) Summary

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

21 CFR 807.92(a):

AUG 22 1997

21 CFR 807.92(a)(1):

* Submitter's name and address:

Osteometer MediTech A/S
Glerupvej 2, DK-2160 Rodovre
Denmark

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

* Contact person:

Ms. Anja Koue
Official Correspondent
Osteometer MediTech A/S
Glerupvej 2, DK-2160 Rodovre
Denmark

* Date this 510(k) summary was prepared: November 5, 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-200 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, is submerged into a soft
tissue equivalent water bath.

The X-Ray generator is driven at 55 Kv, with a current of 0.3

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mAmps. The detector uses a scintillating crystal and a solid state dual energy sandwich detector. A highly stable X-Ray output, together with a source collimation of 1 mm diameter, and excellent pixel resolution, yields images of very high quality.

The typical time to estimate bone mineral content and bone mineral density is approximately 3.0 to 4.5 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 device to which equivalence is claimed; i.e., "To estimate bone mineral content (BMC, grams) and bone mineral density (BMD, grams/cm²).

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 candidate and the DTX-200 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 and the DTX-200 predicate device are identical and use dual X-ray photon absorptiometry (DXA) to estimate bone mineral content (BMC) and bone mineral density (BMD).

*** Soft-tissue equivalent material:**

Both the candidate and predicate DTX-200 devices are identical and use water as soft tissue equivalent material.

*** Calibration:**

Both the DTX-200 candidate device and the DTX-200 predicate device use a line-by-line calibration system, ensuring good precision.

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

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phantom:

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

* Source collimation:

The source collimation for both the DTX-200 candidate device and the DTX-200 predicate device is the 1 mm diameter.

* Reference location:

The reference location for both the DTX-200 candidate device and the DTX-200 predicate device is the 8 mm Ulna-Radius gap.

* Accuracy and precision error:

Accuracy and precision error of the DTX-200 candidate device is comparable to that of the DTX-200 predicate device.

21 CFR 807.92(b);

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 two (2) clinical tests were used to obtain data to establish a reference data base for a reference population of normal American female caucasians ranging in age from 20 to 80 years. These clinical studies were conducted at:

1. Helen Hayes Hospital (West Haverstraw, NY); protocol # 94-12:

* Title: "Determination of Forearm Bone Density in a Normal

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US Population and Comparison of Two New Procedures to Measure Bone Mineral Density".

* Conducted from February 1996 through September 1996.

2. United States Department of Agriculture Human Nutrition Research Center on Aging at Tufts University (Boston, MA); protocol # 3895

* Title: "Mineral Density in a Normal American Population".

* Conducted from March 1996 through October 1996.

Data in a reference population (normal, American, female, caucasians) of a statistically valid quantity of women participating in the two clinical studies were collected using a model DTX-200 bone densitometer to estimate bone mineral content and bone mineral density in the non-dominant forearm of a representative sample of the reference population and included at least 50 persons in ten year peer age groups. The mean and standard deviations of the data was calculated using appropriate statistical methods and was used to establish the reference data base for the reference population.

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:

The standard deviation of estimated bone mineral content (BMC) and bone mineral density (BMD) of the reference population of participating female caucasians is statistically representative (as required by FDA's "Draft Guidance for Review of Bone Densitometer 510(k) Submissions"); i.e., at least 50 people in each ten year age group) of the reference population and the American reference data base (derived from this data) is suitable for use by a health care professional to compare BMC and BMD with age matched peers and for comparison with young adult mean value.

.... END OF 510(k) SUMMARY

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 22 1997

Bert Hudson
Regulatory Consultant
Osteometer Meditech A/S
C/O Shotwell & Carr, Inc.
3003 LBJ Freeway Suite 100
Dallas, TX 75234

Re: K964562
DTX-200 Bone Densitometer
Dated: May 28, 1997
Received: May 29, 1997
Regulatory class: II
21 CFR 892.1170/Procode: 90 KGI

Dear Mr. Hudson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmaman.hun1>.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 96 4562

Appendix G1

FDA's New Form Describing "Indications for Use".

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510(k) Number (if known): Unknown; Not yet assigned by FDA .

Device Name: Model DTX-200 Bone Densitometer

Indications For Use for the device: Estimate bone mineral content (BMC in grams) and bone mineral density (BMD in grams/cm²) in the distal section of the forearm.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ (Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)

David G. Segerson
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number

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