K030330

JUN 2 0 2003

## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92(c).

**Contact Information:** Christopher E. Cann, Ph.D.
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**Date:** January 30, 2003

**Device/Trade Name:** CTXA Hip Extended Reference Data

**Common/Usual Name:** Bone Mineral Densitometer

**Classification Name:** Bone Densitometer, 21 CFR 892.1170, Class II

**Predicate Devices:**

K002113: CTXA Hip Bone Mineral Densitometer

### Device Description

The CTXA Hip Extended Reference Data is an accessory to the CTXA Hip Bone Mineral Densitometer. The CTXA Hip Extended Reference Data is used within the CTXA Hip module to calculate T-scores and percent young normal for any patient, and Z-scores for patients age 20-80 for BMD estimates made using the CTXA Hip module.

### Intended Use

The intended use of the CTXA Hip Extended Reference Data accessory for the CTXA Hip Bone Mineral Densitometry module is to provide a context for the clinical interpretation of a patient's proximal femur BMD estimates. The use of a reference data set and the interpretation of parameters derived by the CTXA Hip module when comparing patient-specific BMD estimates to the installed and selected reference data set is at the discretion of the physician.

### Summary of Technological Characteristics and Comparison with Predicate Devices

The predicate K002113 CTXA Hip Bone Mineral Densitometer Module (CTXA Hip) provides estimates of bone mineral content (BMC) and bone mineral density (BMD) values similar to those obtained from DXA devices. These BMD estimates from the predicate device are compared to a reference database of age 20-39 US Caucasian females to calculate T-scores and percent young normal for patient BMD estimates and Z-scores for patient BMD estimates for ages 20-39. The current CTXA Hip Extended Reference Data is an accessory to CTXA Hip that also is used to calculate T-scores and percent young normal, and also is used to calculate Z-scores for ages 20-80. The CTXA Hip BMD estimates referenced to the CTXA Hip Extended Reference Data reference population are used as an aid to the physician in identifying patients with low bone mineral density and as an aid in determining a patient's fracture risk.

**Summary of Clinical Performance Data**

BMD estimates obtained with CTXA Hip with Extended Reference Data accessory are identical to BMD estimates obtained with the predicate CTXA Hip. T-scores calculated with CTXA Hip with Extended Reference Data accessory are slightly less negative or less positive than those calculated with CTXA Hip, approximately 0.1-0.2 T-score units. This difference is not significant clinically.

**Conclusions**

The CTXA Hip Extended Reference Data is substantially equivalent to the listed predicate device. The clinical interpretation of BMD estimates made with CTXA Hip Extended Reference Data is comparable to that associated with the predicate device.

Signature

Christopher Cann
Printed Name

CEO and Director of Research and Development
Title

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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JUN 2 0 2003

Christopher E. Cann, Ph.D.
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Mindways Software, Inc.
282 Second Street, Fourth Floor
SAN FRANCISO CA 94105

Re: K030330
Trade/Device Name: CTXA Hip Extended Reference Data
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone densitometer
Regulatory Class: II
Product Code: 90 KGI
Dated: May 16, 2003
Received: May 19, 2003

Dear Dr. Cann:

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 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K030330

DEVICE NAME: CTXA HIP EXTENDED REFERENCE DATA

INDICATIONS FOR USE:

The intended use of the CTXA Hip Extended Reference Data accessory for the CTXA Hip Bone Mineral Densitometry module is to provide a context for the clinical interpretation of a patient's proximal femur BMD estimates. T-scores are calculated relative to a US normal female Caucasian reference population age 20-39 years, and Z-scores are calculated relative to a US normal female Caucasian reference population age 20-79 years. The use of a reference data set and the interpretation of parameters derived by the CTXA Hip module when comparing patient-specific BMD estimates to the installed and selected reference data set is at the discretion of the physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030330