DEC 0 4 2001

K002113

## 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:** September 28, 2001

**Device/Trade Name:** CTXA Hip

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

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

**Predicate Devices:**

K894854: QCT Bone Mineral Density Analysis Software
Intended Use: Estimate bone mineral density within the spine.

K883280: Hologic QDR 1000 X-Ray Bone Densitometer
Intended Use: Estimate bone mineral density and bone mineral content at various anatomical sites, including the proximal femur.

K943505: Hologic QDR 3000 X-Ray Bone Densitometer
Intended Use: Estimate bone mineral density and bone mineral content at various anatomical sites, including the proximal femur.

Preamendment: Norland Model 178 Bone Densitometer
Intended Use: An aid to the physician in determining fracture risk.

**Device Description**

The CTXA Hip Bone Mineral Densitometer (CTXA Hip) is a software package intended for estimation of bone mineral content (BMC), in grams, and bone mineral density (BMD), in $g/cm^2$, of the proximal femur. The CTXA Hip uses quantitative computed tomography (QCT) methods to derive bone mass and bone density estimates from 3D CT image data sets. The CTXA Hip is

intended to be used with compatible, whole-body CT scanners and with compatible CT calibration phantoms. BMD estimates are derived in units of g/cm$^2$ equivalent $K_2HPO_4$ density.

**Intended Use**

The CTXA Hip Bone Mineral Densitometer is intended to estimate bone mineral content (BMC) and bone mineral density (BMD) in the proximal femur. The BMD estimates can be compared with CTXA Hip-derived reference data. T-scores are calculated with respect to CTXA Hip young normal female reference data, and the T-scores can be used by the physician as an aid in determining fracture risk.

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

The CTXA Hip Bone Mineral Densitometer Module (CTXA Hip) provides estimates of bone mineral content (BMC) and bone mineral density (BMD) values smilar to those obtained from the predicate DXA devices (K883280: Hologic QDR 1000 X-Ray Bone Densitometer; K943505: Hologic QDR 3000 X-Ray Bone Densitometer) for regions of interest in the proximal femur. CTXA Hip uses the same technical procedures to acquire and calibrate CT image data as are used for the predicate device K894854: QCT Bone Mineral Density Analysis Software. CTXA Hip reference data for young normal US Caucasian females were acquired in a clinical study so that patient results obtained using CTXA Hip can be compared to this normal reference population. The CTXA Hip BMD estimates compared to the CTXA Hip reference population are used as an aid to the physician in identifying patients with low bone mineral density. Additionally, normal data comparisons provide a basis for estimating fracture risk, as is done with the predicate preamendment device Norland Model 178 Bone Densitometer.

BMC and BMD estimates are returned by the CTXA Hip for the following proximal femur regions-of-interest (ROIs): (1) femoral neck, (2) trochanter, (3) intertrochanter, (4) Ward's Triangle, and (5) total hip (i.e., superposition of ROIs 1-3).

**Summary of Non-Clinical Performance Data**

*In vitro* phantom studies with the CTXA Hip indicate a device precision of approximately 0.007 g/cm$^2$ across a variety of CT scanners. These tests also indicate that *in vitro* CTXA Hip BMD estimates are unbiased when expressed as equivalent $K_2HPO_4$ mineral density.

**Summary of Clinical Performance Data**

CTXA Hip clinical studies indicate a long term *in vivo* device precision of 0.011 g/cm$^2$ for total hip and 0.012 g/cm$^2$ for femoral neck regions of interest. Clinical studies were done comparing BMD results from CTXA Hip with results from Hologic QDR1000 and QDR4500 bone densitometers. BMD correlations (Pearson's R) were 0.90-0.97 for the Total Hip region of interest and 0.88-0.95 for the Femoral Neck region of interest. A clinical study was done to collect a set of young normal female reference data for calculation of T-scores for CTXA Hip results.

**Conclusions**

The CTXA Hip Bone Mineral Densitometer is substantially equivalent to the listed predicate devices. The CTXA Hip *in vitro* and *in vivo* performance is comparable to that associated with the predicate devices. The radiation dose associated with the CT study that provides the data set to be analyzed by the CTXA Hip is well within accepted patient dose guidelines.

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
Rockville MD 20850

DEC 0 4 2001

Christopher E. Cann, Ph.D.
CEO and Director of Research
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282 Second St., 4th Floor
SAN FRANCISCO CA 94105

Re: K002113
Trade/Device Name: CTXA HIP, CTXA;
QCT PRO CTXA HIP
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone densitometer
Regulatory Class: II
Product Code: 90 KGI
Dated: September 28, 2001
Received: October 2, 2001

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.

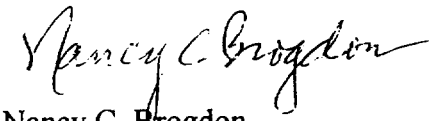
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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 this 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" (21 CFR Part 807.97). 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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K002113/S002

Device Name: CTXA Hip Bone Mineral Densitometer

Indications For Use:

**Intended Use**

The CTXA Hip Bone Mineral Densitometer is intended to estimate bone mineral content (BMC) and bone mineral density (BMD) in the proximal femur. The BMD estimates can be compared with CTXA Hip-derived reference data. T-scores are calculated with respect to CTXA Hip young normal female reference data, and the T-scores can be used by the physician as an aid in determining fracture risk.

(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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K002113